RTE PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, the CSI will

1. Define
   - High risk product
   - Intensified
   - Low risk product
   - Medium risk product
   - Other RTE
   - Targeted

2. State the purposes of FSIS sampling.
3. Give the names and locations of the 3 FSIS Field Service Laboratories.
4. Select, from a list, those products that may be subject to sampling under the targeted verification program.
5. Describe how FSIS Form 7355-2 is applied.
6. State how FSIS notifies plant management when a sample is collected.
7. Demonstrate the sequence for properly packing a sample.

Overview

This module presents ready-to-eat (RTE) product sampling currently used by FSIS. It specifically covers

- The purpose of the FSIS Directive 10,240.3
- New terminology
- Determining the risk of product and processing operations
- FSIS verification testing programs
- Sample collection procedures
- Preparation and shipping samples

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused foodborne illness. As an agency dedicated to protecting the public health, FSIS has used science to keep pace with, and to keep ahead of, these pathogens. Detecting the pathogen is the first step. From there, FSIS works with other governmental agencies, academia, industry, and consumer groups to set policy and establish guidelines and performance standards to reduce or eliminate the pathogen from meat and poultry products. During the

1980's, *Listeria monocytogenes*, which previously was known as a contaminant of dairy products and some other foods, began to emerge as a problem in processed meat and poultry products. In 1998, State Health Departments and the CDC investigated an outbreak of food borne illness in which hot dogs and possibly deli meats were implicated. Investigators isolated the outbreak strain from an opened and previously unopened package of hot dogs. When all was said and done, CDC reported 101 illnesses, 15 adult deaths, and 6 stillbirths associated with this outbreak.

Another outbreak in 2000, was caused by turkey deli meat and was linked to 29 illnesses that resulted in 4 deaths and 3 stillbirths. Investigations of these and other outbreaks have proven that not only the products, but the production environments as well, are sources of pathogens that can take a serious toll on public health. Although *Listeria monocytogenes* (*Lm*) has been known to cause foodborne illness associated with meat and poultry since 1982, it is only recently that large volumes of federally inspected meat and poultry have had to be recalled from commerce, with many of them associated with food borne outbreaks. Each package of federally inspected product that is recalled bears the mark of inspection, which the public has come to trust as a sign that the product is safe. FSIS intends to maintain that public trust. To that purpose, FSIS samples products, and is beginning to sample the production environment, to detect pathogens in RTE food and processing establishments.

By sampling RTE products in federally inspected meat and poultry plants, you are verifying the plant's HACCP system effectiveness to produce wholesome, unadulterated product.

As FSIS is continuously improving its sampling protocol and techniques, updating sampling programs, and developing more rapid means of reporting results, the policies will change accordingly. **FSIS directives and notices for current sampling projects and programs contain policy details and specific instructions for you to follow** (see Attachment 2). Policy changes rapidly and amendments and new issuances are developed to keep you informed. You should read issuances when they are published so that you are at least familiar with the fact that a notice or directive was recently issued that dealt with sampling. Then you will know to read the updated issuance when you need to actually collect a sample that may be affected by the information in the issuance.

FSIS is responsible for maintaining effective inspection and enforcement programs to assure consumers that their supply of meat and poultry products is safe, wholesome, unadulterated, properly labeled and produced in a sanitary environment. FSIS sampling activities play an integral role in verifying the plant's compliance with regulatory requirements.

FSIS's microbiological testing protocol is designed to verify that HACCP programs are effective in controlling harmful microorganisms (pathogens) in meat and poultry products. The focus of this module is on the microbiological analyses of ready-to-eat meat and poultry food products for the presence of *Salmonella, Listeria monocytogenes,* and for certain products, *E. coli* O157:H7.

PBIS Procedure Code 05B02

Procedure 05B02, although still under the "Economic Sampling" heading, encompasses microbial analyses with a direct bearing on food safety and public health. All the samples are requested from OPHS (Office of Public Health and Science). The directed sample requests for microbial analyses are on the Requested Sample Programs Form, 10,210-3. Sometime in the near future, this form will be completed on-line.

The 05B02 procedure is also used for directed samples that are not a food safety concern (hence, the "Economic Sampling" heading). These are import samples for food chemistry analyses. Therefore, it is not a simple matter of stating that Other Consumer Protection (OCP) requirements are verified under 05B01 sampling and only health and safety requirements are verified under 05B02 sampling. Procedure 05B02 actually addresses both, depending upon the program area (domestic or imports).

The front line supervisor, district office, or Washington headquarters (not just OPHS) may also initiate the 05B02 samples. It is important that you recognize the difference between procedures 05B01 and 05B02, even though there is overlap between these two sampling procedures.

05B02 as it Relates to Food Safety

FSIS verifies the adequacy of an establishment's HACCP system by determining whether HACCP plans meet the requirements of §417 and all other applicable regulations, and whether the system is operating as intended. Verification activities include, but are not limited to, collecting and testing RTE products for microbial hazards. RTE products are intended to be consumed without any further safety preparation steps. FSIS Directive 10,210.1, Unified Sampling Form, lists the products and pathogens and toxins for which FSIS may collect and test samples. For example, FSIS may analyze a ready-to-eat meat and poultry product for *Salmonella* **and** *Listeria monocytogenes*. Plus, if the product is a cooked beef pattie, or dry, semi-dry fermented sausage, then it will also be analyzed for *E. coli* O157:H7.

For directed sample requests, the project name is specified on the request form. Unless a specific product is requested, the Inspector-in-Charge or front line

supervisor should oversee sample collection to ensure that different products are sampled each time sample request forms are received and that risk associated with certain types of product is considered in the sample selection decision.

Since a directed sample request is ***not*** a scheduled procedure, 05B02 is recorded as unscheduled on the Procedure Schedule.

FSIS Directive 10,240.3 - Microbial Sampling of RTE Products

The purpose of FSIS Directive 10,240.3, Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program (see Attachment 7), besides canceling the 10,240.2 directive, is to provide inspection personnel with specific instructions for sampling RTE meat and poultry products produced in official establishments as one means of verifying that a HACCP plan is producing RTE products that are safe, wholesome and unadulterated.

This directive contains some new terminology such as post-lethality exposure and environmental sample, assigns a risk category (high, medium, or low) to certain RTE products, and provides instructions for sampling food contact surfaces and indirect or non-food contact surfaces.

This directive also provides procedures for CSIs to follow when establishments that produce certain RTE products incorporate *L. monocytogenes* or indicator organism[1] testing into their HACCP plans, Sanitation SOPs, or prerequisite programs.

In Part III of this directive, you will find instructions to follow when a sample tests positive for *L. monocytogenes*; however, that portion of the directive is discussed in the Documentation and Enforcement part of this training and not in this module.

[1] Indicator organisms are bacteria used to determine objectionable microbial conditions of food, such as the presence of potential pathogens, as well as the sanitary conditions of food processing, production or storage areas. There are certain criteria which determine the value of an indicator organism, such as it should not be present as a natural contaminant of the product or environment, it should be easy to grow and differentiate in analyses, and it should be able to withstand the processing treatments of the food and environment in a manner similar to the pathogens of concern. [See Banwart.] *Listeria* spp. are such indicators for *Listeria monocytogenes*.

New Terminology

Pathogen of public health concern is any microorganism or other biological agent that has the ability to cause disease in humans. For the purposes of the FSIS RTE verification testing program, these pathogens include *E. coli* O157:H7, *L. monocytogenes* and *Salmonella*.

High or medium risk products are specific to the RTE verification testing program. These ready-to-eat meat and poultry products are defined as

- High risk - Deli-type products that include, but are not limited to, products that either are sliced in the establishment or likely will be sliced at retail (e.g., at a deli counter), such as cured ham, cooked ham or turkey, bologna, luncheon meat, pastrami, luncheon meats, meat and poultry deli salads, pâtés, and meat spreads.

- Medium risk - Hot dog-type products that meet the standard of identity found in 9 CFR 319.180 and 319.181, or a variation of these standardized products.

Low risk products are specific to the RTE verification testing program. These meat and poultry products are deli-type products (i.e., products that either are sliced in the establishment or will be sliced at retail) and hot dog type-products that have been formulated or are produced and distributed under conditions validated to prevent the growth of *Lm.*

Products may be formulated or produced and distributed under conditions validated to prevent the growth of *Lm* by

- maintaining pH < 4.5;
- maintaining pH < 5.0 + refrigerated storage;
- maintaining a_w <0.90;
- maintaining a_w <0.92 + refrigerated storage;
- maintaining a_w <0.95 + pH <5.5;
- containing an antimicrobial agent (e.g., sodium or potassium lactate, sodium diacetate) that is validated through scientific studies to inhibit growth of *Lm*;
- maintaining storage at or below 0°C (32°F) and are labeled “Keep Frozen” and do not meet the criteria for NRTE; or
- receiving a post-lethality treatment that has been validated as being effective in eliminating *Lm* (these are applied to sealed and packaged final product and are intended to further reduce the level of potential pathogens in RTE products).

Validation is demonstrated through scientific articles, university studies for the plant’s processes, in-plant data, etc.

Other RTE products are all RTE products that are not deli-type or hot dog-type products. There is no risk assigned to these products. Most of the RTE products sampled under 05B02 are "other RTE" products.

High or medium risk operation are

- All large plants (500 or more employees) that produce any amount of high or medium risk product.

- Any small or very small plant (less than 500 employees) that produces a large volume (1,326,000 pounds annually) of high or medium risk product or produces any amount of high and medium risk product, and

    - has a history of multiple or recurring sanitation (procedures 01B, 01C, 06D) noncompliance records (NRs) in the area of the facility where RTE product is exposed to the environment;

      Or

    - is operating under conditions that have historically been associated with findings of *L. monocytogenes* on product or in the environment (construction activity) and does not have a science-based control program to address this situation.

Low risk operation is any plant that produces low risk product, and

- Does not have a history of multiple or recurring sanitation (procedures 01B, 01C, 06D) noncompliance records (NRs) in the area of the facility where RTE product is exposed to the environment;

  and

- Has a science-based control program to address conditions that have historically been associated with findings of *L. monocytogenes* on product or in the environment (construction activity).

Food contact surface is specific to the RTE verification testing program, and consists of all equipment or utensil surfaces with which exposed RTE product has direct contact (e.g., conveyor belt, tabletop, knife blade). A food contact surface does not include aprons, mop handles, gloves, and other items that may have indirect or potential contact with exposed RTE product.

Food contact surface samples are a collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

Environmental samples are samples from surfaces that have

- indirect or potential contact with exposed RTE product in the RTE production area (mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or

- non-contact surfaces in a RTE production area (e.g., floors, drains, walls, overhead structures).

Lethality treatment is the necessary reduction in the number of pathogens to result in a product that is safe for consumption without further cooking or application of another lethality treatment to destroy pathogens.

Post-lethality exposure is exposure of RTE product directly to a food contact surface after the lethality treatment. Such exposures generally are the result of slicing, peeling, or re-bagging product that previously underwent a lethality treatment to result in RTE status.

Post-lethality treatment is a lethality treatment after post-lethality exposure that is applied to the final product or sealed package and is intended to further reduce the level of potential pathogens, such as *Lm*, in RTE product.

RTE production area is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for *L. monocytogenes* or indicator organisms.

RTE product samples are a collection of sampled RTE product that represents the sampled lot. The samples are taken from product that has passed the plant's pre-shipment HACCP review. The sampled product should be in its consumer-ready package whenever possible. When this is not possible (e.g., only bulk product is being produced and the immediate container is too large to ship), you may permit the plant to short-weight or slack-fill the immediate container. In such cases, the sample must be produced and packaged in the same way as the product that it represents; the only difference is that the contents of the package are less than the contents of the packages that it represents. Minimum sample sizes for analyses are defined in FSIS Directive 10,210.1 under "collection instructions".

Prerequisite programs, for the purposes of the FSIS RTE verification testing program, are procedures other than SSOPs that are designed to provide the basic environmental and operating conditions necessary for the production of safe, wholesome food and to control *L. monocytogenes*. Because of its prerequisite program, an establishment may decide that a food safety hazard (e.g., *L. monocytogenes*) is not a hazard likely to occur in its operation. The establishment would need to document this determination in its hazard analysis and include the procedures (e.g., regular auditing and documentation) it employs to ensure that the program is working and that the hazard is not likely to occur 9 CFR 417.5 (a)(1).

FSIS Verification Testing Programs

FSIS is redirecting its verification efforts, including laboratory resources, regarding the sampling of RTE products. In this regard, FSIS has established a **risk-based verification sampling program** in which products posing the highest risk for pathogens affecting public health are selectively scrutinized by FSIS in an effort to better ensure that the food safety systems are effective.

The verification testing programs are
- Intensified,
- Targeted,
- Low-Targeted, and
- Non-Targeted.

Intensified Verification Testing Program

The **intensified** verification testing program includes, but is not limited to, high, medium, and low risk products (deli-type and hot dog-type products) where the establishment does not have a science-based program addressing *Lm* in its RTE product and RTE product environment. More details about science-based programs are given later in this module.

Intensified sampling consists of collecting multiple intact product samples, food contact surface samples, and environmental samples (indirect food contact surface samples and non-product contact surface samples). Samples collected under the intensified format are intended to be collected from the establishment's current day's production from one lot of product.

At this time only specially trained FSIS personnel will be collecting samples for the intensified verification testing program. You may be asked to assist the sampling team in the completion of sample forms and packing and mailing samples.

The intensified verification testing program is coordinated through the District Office. You perform product sampling for targeted, low-targeted, and non-targeted verification per normal sample requests. If any change in the plant or plant operations (new products, construction, etc.) occurs that impacts the verification program status, notify your front line supervisor.

Targeted Verification Testing Program

The **targeted** verification testing program includes high and medium risk RTE product where the establishment

- has a science-based program addressing *Lm* in the product, on food contact surfaces, and in the RTE environment; **and**
- has its science-based program in the HACCP plan, Sanitation SOP or prerequisite program; **and**
- must share its testing results with FSIS.

Targeted testing also includes ***other*** RTE products ***not*** in low-targeted or non-targeted verification programs. (Remember, these other RTE products do not have a risk assigned to them at this time.)

FSIS randomly collects one sample of RTE product and tests for pathogens of public health concern. You carry out HACCP, SSOP and prerequisite program verification activities, including the review of records and laboratory results, to verify the establishment is properly addressing the control of *L. monocytogenes* in RTE products and in the areas of the plant where RTE products may be exposed to the environment.

Low-Targeted Verification Testing Program

The low-targeted verification testing program is for *low risk product*. Included are deli-type and hot dog-type RTE products that are formulated or produced and distributed under conditions validated to prevent the growth of *Lm*. Plants must

- have a science-based program addressing *Lm* in their HACCP plans, SSOPs or prerequisite programs, ***and***
- share their testing results with FSIS to qualify for the low-targeted verification program.

FSIS randomly collects one sample of RTE product and tests for pathogens of public health concern. You carry out HACCP, SSOP and prerequisite program verification activities, including the review of records and laboratory results, to verify the establishment is properly addressing the control of *L. monocytogenes*

in RTE products and in the areas of the plant where RTE products may be exposed to the environment.

NOTE: *Plants that produce **low risk product** that have a science-based program in place but **do not** share their testing results with FSIS are sampled in the **targeted** verification testing program.*

Other RTE products, those that have not been assigned a risk, may be sampled in the targeted, low-targeted, or non-targeted verification testing program. In order for these "other" RTE products to be sampled in the low-targeted program, they must have been formulated or produced and distributed under conditions validated to prevent the growth of *Lm.*

Non-targeted Verification Testing Programs

The **non-targeted** verification testing programs cover those products that inherently have such a low water activity or high salt concentration that pathogens have rarely, if ever, been associated with them. Historically, FSIS has sampled these products on a limited basis, and it will continue to do so. These include lard, margarine, mixtures of rendered animal fats, popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, pickled pigs' feet, or product labeled "For Further Processing" in which the product is expected to receive a lethality treatment at another official establishment. In actuality, the latter does not need to have "For Further Processing" on the label as such. If the producing establishment can demonstrate that the product is expected to receive a lethality step and the receiving establishment assumes that *Lm* may be in the product, then it is considered "For Further Processing" and falls into the non-targeted testing program.

All verification testing programs have at least one thing in common besides testing for pathogens of public health concern, which is that plants must have completed the pre-shipment review before collected samples are sent to the laboratory for analyses. More will be said about this later in the module.

Science-based Programs

As stated earlier, establishments that produce high or medium risk products are sampled in the intensified verification testing program. If an establishment has a science-based program addressing *Lm* in product, on food contact surfaces, and in the RTE environment, and the program is in the HACCP plan, SSOP, or prerequisite program supporting the hazard analysis, then FSIS will sample its high and medium risk product in the Targeted verification testing program. If the

establishment produces a low-risk product and has a science-based program as stated above, FSIS will sample the plant's product in the low-targeted verification testing program.

There is no scripted definition of a science-based program. FSIS wants to allow the plants the latitude to develop their own systems. Plants ***may*** choose to design a science-based program which ***may*** include environmental (indirect or non-product contact surfaces) and food contact surface testing and make that program part of their SSOP. They may have a program for testing product as part of their HACCP plans. Specific organisms may include indicator organisms, *Listeria* ssp., or *Listeria monocytogenes.*

NOTE: *These are listed as options. However, the plant must address the presence of* Lm *in a science-based program since the purpose of such a program is to* ***control*** Lm *in RTE products.*

The **key factors** FSIS expects plants to address in these science-based programs are

- Is there a written program designed to look diligently for the organism?
- If the organism or an indicator organism is found, what are the procedures for addressing product that is affected by positive results?
- What corrective actions are implemented to eliminate the organism from product, food contact surfaces, and the environment once it is found?
- What are the verification procedures to demonstrate that the corrective actions are effective?

If the plant has a food contact surface and environmental (i.e., indirect or non-food contact surface) sampling program, it should be designed to test all food contact equipment within the RTE environment over time. "Over time" does not mean within a period of years. The program needs to be designed to find the organism if it is there and to remove the conditions that allow it to persist in the environment.

Establishments need to keep in mind the number and types of equipment within each process, exposed RTE product storage areas, flow of product, etc., in designing their science-based programs. For example, if a plant produces a cook-in-bag product and does not open the bag prior to shipping (never exposes that product post-lethality to the environment), then testing the environment has no impact on this process since the product is not exposed to potential contamination.

Another example is a plant with a validated post-lethality pasteurization step designed to reduce or eliminate *Lm* that may occur post-lethality (the plant

would need to support why this would not be a CCP). Once validated, as long as the plant meets the critical limit, there is no need to do further testing beyond that which is necessary to demonstrate that the post-lethality treatment is effective within the operating conditions of the plant. The focus here would most likely be on verifying the effectiveness of the post-lethality treatment rather than on the sanitary conditions that are prior to the post-lethality treatment.

NOTE: *Some establishments may employ a lethality treatment after exposure of the product to the environment, followed by limited exposure of this product to the environment prior to packaging. Such establishments may wish to have these systems designated as a post-lethality treatment. These situations need to be assessed on a case-by-case basis. FSIS does not consider such operations to fit within the intent of a post-lethality treatment. Such situations may likely require substantial on-going verification testing of the food contact surfaces and the environment in areas from post-lethality treatment to final packaging.*

Corrective actions to be taken when *L. monocytogenes, Listeria* ssp. or indicator organisms are found are an important part of any science-based program design. If an establishment has a positive result from an equipment sample, what actions will it take? Is the establishment performing a special recleaning of that piece of equipment and then resampling? In addition to resampling that piece of equipment, does the program call for the routine sampling of other areas? If the establishment continues to find *L. monocytogenes, Listeria* ssp. or indicator organisms on equipment or in the environment, is that triggering product testing? Are product “hold and test” procedures defined?

As stated earlier, there is no scripted definition of a science-based program. There will be many variations from one establishment to another. Your job is to determine that the establishment’s science-based program meets the intent of the directive when determining whether RTE products should be sampled under the intensified, targeted or low-targeted verification testing programs. As always, if you have questions or concerns you may call the Technical Service Center.

Plant Sampling and Science-based Programs

Some plants may have their own sampling programs. Plants may sample for various reasons (checking suppliers, to satisfy contracts with customers, etc.), but most commonly they sample to verify their processes. If the plant has its own testing program, these sampling programs may or may not be included in the

plant's SSOP or HACCP plan[2]. If they are not included in these, then the plant is under no obligation to share analyses results with you. Again, the plant is not required to notify FSIS of a positive sample in this case, but the plant **is** required to take corrective actions that meet the requirements of §417.3 each time a positive result is received. If the plant shares the data, you should review it periodically. If you find the plant has had a positive result for a pathogen of public health concern, verify that the plant has taken corrective actions required by 417.3 (a) or (b).

If the plant has a science-based program which includes product testing, food contact surface testing and environmental testing in RTE areas, the testing protocol for the product samples could be part of the HACCP plan. The food contact surface and environmental sampling protocol could be addressed in the SSOP (unless the plant opts to also include this testing in its HACCP plan). As stated earlier, there are a variety of ways a plant may document and support its science-based program in its food safety system.

When a positive plant test result indicates a deviation from a critical limit, the plant does not need to notify you that it had a positive test result, however, when you are aware that there was a positive result you will verify the plant's corrective actions as per §417.3(a) if a deviation from a critical limit or §417.3(b) if an unforeseen hazard.

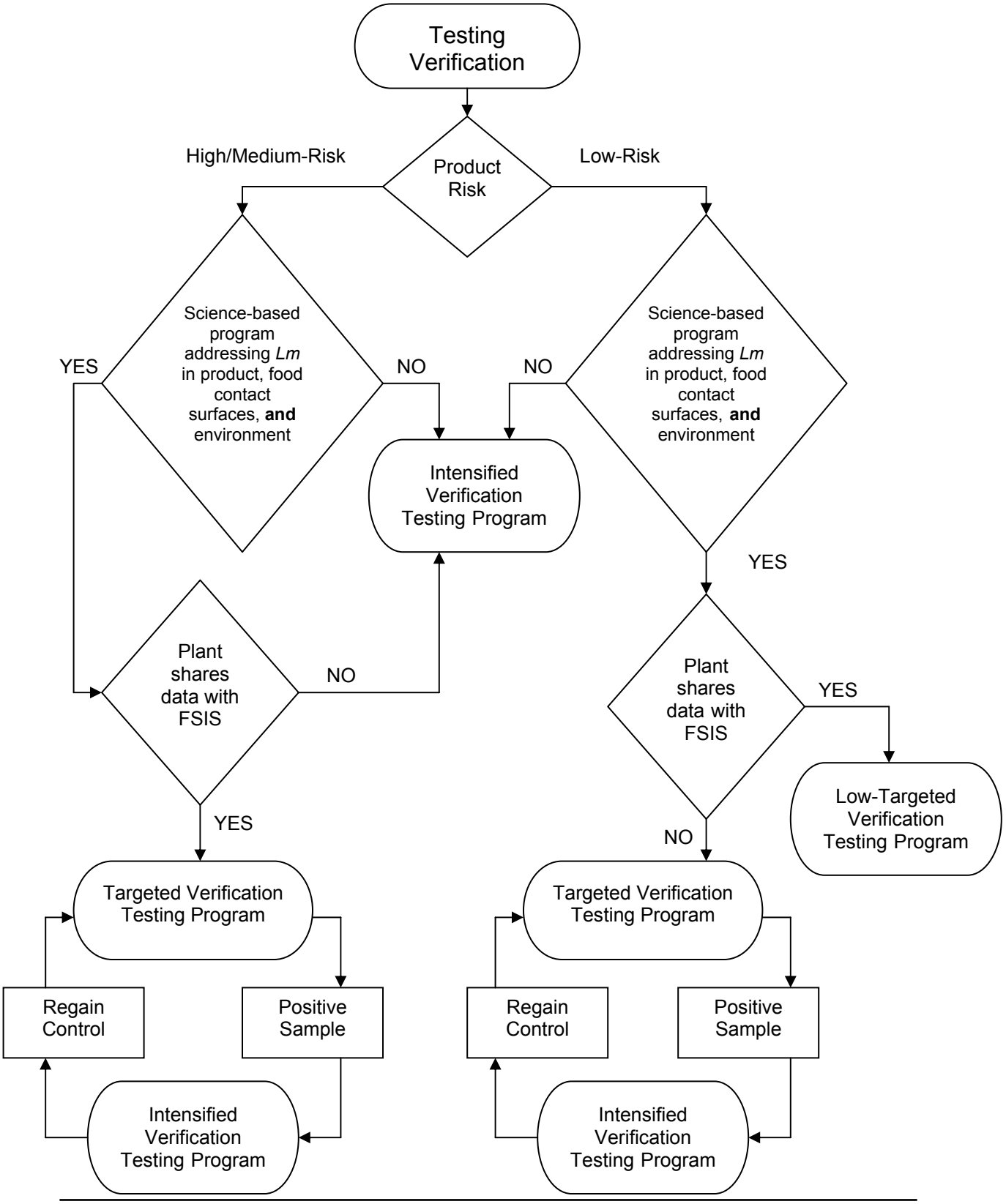
Some plant sampling programs may not target *L. monocytogenes*, but rather *Listeria* or an indicator organism. The presence of *Listeria* or indicator organisms shows that *Listeria monocytogenes* could be in the plant because the same conditions that eliminate *Lm* also eliminate indicator organisms. Therefore, if the indicator organism has been eliminated, chances are good that *Lm* has been eliminated also.

[2] Most commonly, product-sampling programs are in the HACCP plan, because the programs are usually testing product, which has a direct bearing on food safety. If it is environmental testing, it is more commonly found in the SSOP if the plant chooses to put it into one of the regulatory required documents (SSOP or HACCP plan). If the program is mentioned in the hazard analysis as part of the supporting documentation, then records need to be provided as required in §417.5(a)(1) to continue to support why the hazard is not reasonably likely to occur.

On an on-going basis, you are to review the laboratory results of the plant's testing program. If multiple positive samples for indicator organisms are detected for food contact surfaces, either within consecutive samples or non-consecutive samples within a relatively short time span, and the plant did **not** take the corrective and preventative action outlined in its plan, you should immediately contact your front line supervisor.

All decision-making documents and written procedures, along with the test results, should be made available to you for review. Verify that, if the sample came from a food contact surface, the plant took corrective and preventive measures and increased the number of food contact surface samples it takes to ensure that the corrective and preventive actions were effective. More information about actions you take when a plant sample tests positive is given in the Documentation and Enforcement Module.

Flowchart: Determining Testing Verification Program



Workshop I

1. A plant produces summer sausage with a pH of < 5.0 and refrigerates the product. This plant has no science-based program. In which testing verification program does this product belong?

    a. Intensified
    b. Targeted
    c. Low-targeted
    d. Non-targeted

2. A plant produces polish sausage. This plant has a science-based program that includes product testing, as well as testing of both product contact and non-product contact environmental surfaces. The plant shares the information with inspection personnel. In which testing verification program does this product belong?

    a. Intensified
    b. Targeted
    c. Low-targeted
    d. Non-targeted

3. A plant produces pastrami with a post-lethality treatment that has been validated as being effective in eliminating *Lm*. This establishment has a science-based program that includes product testing, product contact surfaces and non-product contact surfaces. The establishment shares the information with inspection personnel. In which testing verification program does this product belong?

    a. Intensified
    b. Targeted
    c. Low-targeted
    d. Non-targeted

4. A plant produces fully cooked fajita meat with a post-lethality treatment that has been validated as being effective in eliminating *Lm*. This establishment has no science-based program involving testing of product, product contact surfaces, and non-product contact surfaces. In which testing verification program does this product belong?

    a. Intensified
    b. Targeted
    c. Low-targeted
    d. Non-targeted

5. FSIS sampling is done to

   a. verify that FSIS performance standards and regulations are met.
   b. validate HACCP plans and compare results to plant analyses.
   c. generate public support.
   d. monitor in-plant activities.

6. PBIS procedure code 05B02 will never appear on your procedure schedule if you are assigned to a plant that does produce RTE product.

   a. True
   b. False

7. Ready-to-Eat chicken patties are analyzed for (circle all that apply)

   a. *E. coli* O157:H7.
   b. Salmonella.
   c. L. monocytogenes.
   d. Staphylococcus enterotoxin.

8. When a plant has a science-based program for sampling RTE product as part of the HACCP plan, you do not have to collect RTE samples.

   a. True
   b. False

9. Low risk products are only deli-type and hot dog-type products that are formulated or produced and distributed under conditions validated to prevent the growth of *Lm*.

   a. True
   b. False

10. Roasted whole chicken (shipped refrigerated, not frozen) would be sampled in the Targeted verification program, unless the plant has a science-based program that addressed *Lm* controls in the product and the environment and shares its sampling results with FSIS.

    a. True
    b. False

11. You receive a 10,210-3 for RTE product. You review the project number and select fully-cooked beef patties. The lab will analyze the patty sample for *Salmonella*, *L. monocytogenes*, and

    a. Staphylococcus enterotoxin.
    b. *E. coli* O157:H7.
    c. *Campylobacter*.
    d. no other microbe.

12. Does a sample test result that is positive for *Listeria* spp. microorganisms indicate that the product is adulterated?

    a. YES
    b. NO

    Justify your answer.

13. When a plant has a science-based program for sampling RTE product for *Lm*, and it receives a positive, is it required to notify you?

    a. YES
    b. NO

14. Polish sausage is a type of product that has not been assigned a risk and would be sample as an "other RTE product".

    a. True
    b. False

15. Plant "A" makes a cooked Italian sausage and sends it to plant "B" where it will be used make a "Spaghetti sauce with Italian sausage". Plant "B" gives this product a lethality treatment. In this scenario, the Italian sausage at plant "A" would be sample in the Non-Targeted Verification Program.

    a. True
    b. False

16. Establishment 38 produces the following;

Bacon

Bologna

Country cured hams

Fresh breakfast sausage

Frankfurters

Cooked Italian sausage

Summer Sausage

Use the Flowchart: Determining Testing Verification Program to help you answer the following questions about the above products.

a. You receive FSIS Form 10,210-3. In block 14, the project code is Targeted. Circle the products you **might** select to sample, assuming all products are available during the sampling time frame indicated in block 4.

b. At the same plant, you receive another 10,210-3 with a project code of Low-targeted in block 14. Mark an "X" next to the products you **might** select to sample, assuming all products are available during the sampling time frame indicated in block 4.

c. Of the products you selected as RTE, which products would have the lowest risk of being a food safety concern? Write the products below.

Sampling Programs

The Agency takes the stance that no pathogens of public health concern should be on RTE product, since there should be a lethality step in the process that produces the product. FSIS tests RTE products for pathogens because of the public health impact (there could be a breakdown in the lethality step, or post-lethality contamination may occur and the plant has no additional steps to destroy microorganisms). FSIS currently samples RTE products for *Listeria monocytogenes*, *E. coli* O157:H7, and *Salmonella*.

All RTE products that bear the mark of inspection are subject to testing. Currently the processing categories containing RTE products are 03E, 03F, 03G, and 03I. OPHS no longer uses process categories when scheduling RTE directed sampling. Now directed sampling requests ask for RTE products in the intensified, targeted, low-targeted, and non-targeted verification testing programs. Product may be heat-treated, fully cooked, dried, pickled or a combination of these processes and be appropriately labeled as ready-to-eat. Determining whether a product is ready-to-eat or not-ready-to-eat should be as simple as looking at how the product is labeled. It is possible that a company that makes a fully cooked sausage could market it as a NRTE product. As a result, the product would not be sampled as a RTE product. In these situations, we would expect the company's HACCP plan to support its decision (i.e., no biological hazard in the hazard analysis that is eliminated with the cooking (lethality) step). You must be knowledgeable regarding the plant's hazard analysis, HACCP plan, various processing procedures and how products are labeled in order to select appropriate samples to meet the RTE sampling initiatives. It is your responsibility to know in which verification testing program to sample a RTE product.

Terminology Used in Sampling

Affected Product
This is any product that represents the sampled lot, as well as product that was produced in the same time frame with the same process and equipment between complete clean-ups. If a sample analysis yields a positive result, then any product produced with the same process/equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment. Generally, this intervention is a complete and/or thorough cleaning and sanitizing operation.

For example, if a RTE product verification sample analysis was positive for *Salmonella,* the cause may be undercooking. In this case, any product that was in the oven with the product that tested positive is considered part of the "affected" product, even if it is a different lot and a different type of product.

Aseptic
"Aseptic" means free from pathogenic organisms. An aseptic technique implies that you do not add any organisms (pathogenic or not) to the sample when it is collected. It does **not** imply that the **sample** is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample ***or*** the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is ***intact***. Wash and sanitize your hands before collecting an intact sample. But, it is not necessary for you to sanitize the area and put on gloves. Good personal hygiene is **essential** anytime a sample is collected, whether it is intact or not.

Intact
This is product in the final packaged form (immediate container) in which it will be shipped. The lab receives the sample in the same immediate container that the consumer will, so whatever is in the product the lab gets is what is in the consumer's product, too. Some products may be produced with components other than meat or poultry, such as RTE frozen dinners. The meat and/or poultry component may or may not be separate from nonmeat/nonpoultry components in these finished RTE products. If the product has the meat portion separated into a compartment (frozen dinners, Lunchables, etc.), then you must ensure that enough meat is available for the analyses. You need to consult the guidance in FSIS Directive 10,210.1 regarding the amount of product to submit. Several packages may need to be sent for the requested sample so that the laboratory has enough meat or poultry to run the analyses.

Sometimes intact products may be very large. If the situation warrants, you may collect a slack-filled or short-weight package to represent the lot of product sampled. Properly collected slack-filled or short-weight packages are considered intact for sampling purposes (see short-weight or slack-filled). If this is not an option, contact the lab via Outlook and request a shipper large enough to contain the size sample you need to collect.

Recall
A recall is a plant's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery.

Product that is adulterated and has left the establishment's control may be subject to a recall. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the Recall Management Division (RMD) of all factors in the situation. All recalls of meat and poultry products are voluntary. FSIS Directive 8080.1 gives additional details on recalls.

Retain
When product is placed under a regulatory control action (§500.1) in an establishment under FSIS jurisdiction, it is considered retained. Retaining product is one form of a regulatory control action (§500.2). When a retain tag is used, a Noncompliance Record (FSIS 5400-4) is used to document any noncompliance associated with that official control action.

Sample
A sample for RTE products is a collection of product that represents a larger group (the sampled lot) that has passed the plant's pre-shipment HACCP review. The FSIS sampling activity is a verification of the effectiveness of the plant's food safety system. The collection of the sample must not interfere with the plant's ability to take any corrective actions related to its food safety system prior to the sample being submitted to the laboratory.

Sampled lot
This is the amount of product represented by the sample. The plant defines the lot. For microbial issues, the actual (affected) product represented by the sample may be from clean-up to clean-up. Often, factors like the plant's coding system, the pathogen of concern, the processing and packaging, the equipment, the plant's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample. It is important for you to have knowledge of the plant's lotting system in order to be able to provide adequate prior notification to plant management when directed to collect a sample.

Sample unit
This is an individual package or container. It may take several sample units to make up one sample, depending upon the amount needed for the analysis.

Short-weight or slack-filled
An intact sample is one that is packaged as distributed by the producer. A short-weight or slack-filled container meets the definition of an intact sample, but with less product (e.g., a liner from a bulk package which contains approximately 2 lb of product, folded down and sealed in the same manner that the bulk product is normally packed to prevent product contamination). A short-weight or slack-filled sample is one that has progressed through all the production steps that the normally packed bulk product goes through (the size of the individual product is not changed in a way that would affect the processing parameters of the product). Because it must be produced in the same way as the rest of the product in the lot, you cannot fill the container for slack-filled or short-weight samples, the plant must do this. If there are questions regarding collecting a sample, discuss this with your front line supervisor or seek guidance through the TSC

Note: A short-weight or slack-filled sample may appear to the lab as a non-intact sample and as such will be discarded if you do not indicate that it is short-weight or slack-filled on the form in block 28. OPHS recommends that you provide additional information when a sample does not appear intact because of the way the company packages product for the consumer (e.g., wrapped in butcher paper). In these situations, write in block 28, "This is an intact sample".

Subsequent production
All product produced after the sampled lot is produced is considered subsequent production. It s not usually part of the sampled lot, but it may or may not be affected product.

Sampling

FSIS sampling refers to you physically collecting product that represents a product type and submitting it to a lab for an actual analysis. Establishment size, type of product, volume of product, history of sanitation NRs, and operating under conditions known to promote growth of *Lm* (e.g., construction), are factors FSIS takes into consideration when scheduling sampling.

The lab is completely dependent on you to properly collect, prepare, and ship the sample. The forms that accompany each sample must be the correct ones for the sample request and must be accurate and completely filled out. Your role is vital regarding sampling. The information entered on the form becomes part of a legal document. If required information is missing or incorrect, the form may not be legally defensible in a court of law and therefore, the sample will be discarded.

Currently, there are three ways that sampling is initiated - inspector-generated, OPHS directed, and special projects.

Inspector-generated samples are initiated by FSIS in-plant personnel and not by OPHS or as a result of policy. You may base this on your own suspicions. For example, is there cause to suspect that the ready-to-eat product might have been contaminated with *L. monocytogenes*? You and your front line supervisor (with concurrence of the District) will determine when inspector-generated sampling should occur. Before a sample is taken, you must obtain a FSIS Form 10,210-3 from OPHS. FSIS Form 10,210-3 (Requested Sample Programs) is the only form accepted by the laboratory for ready-to-eat sample submission. If you use any other form, the sample will be discarded.

OPHS directed samples are selected when policies, guidelines, or supervisory channels dictate that certain products need to be sampled, and when sample requests are received in the mail. OPHS uses only FSIS Form 10,210-3 (Requested Sample Programs). The specific product or product category is

based on the specific sampling. For OPHS directed samples, the product history/risk determines the sampling.

Special project samples are taken when FSIS is alerted to a foodborne illness outbreak by a state or local government, or when there is a special project.

Steps in Sampling

There are 5 general steps in actually sampling product.

1. Determine product to sample
2. Notify plant management
3. Collect the sample
4. Complete the form and package and mail the sample
5. React to results

Step 1: Determine Product to Sample

You determine which product to sample by knowing the plant's processes and how product is labeled. Before collecting a sample, review the notices or directives covering that sample type or program. Use the project code in block 14 of the form and follow the corresponding instructions found in FSIS Directives 10.240.3 and 10,210.1, Amend 5 (or most recent version of this Directive), for collecting and shipping samples. A directed sample request may have additional instructions printed in block 18 and block 28 of the sample request form (see Attachment 4 of this module for a copy of FSIS Form 10,210-3)[3].

In order for the sample to be truly representative of a lot, every attempt must be made to avoid taking a sample that is biased (i.e., nonrandom). One of the best ways to ensure randomness is to mentally number all of the boxes or containers in the lot and then use a random number table or generator to determine which sample to take.

Selecting Samples

Select your samples using the guidelines in FSIS Directive 10,210.1 and on FSIS Form 10,210-3 (block 18) for the type of product to sample. Block 18 lists special instructions for you to follow. These may differ depending upon the request.

[3] It is not necessary to routinely collect lard, margarine, or lard margarine, mixtures of rendered animal fats, popped pork skins, pork rinds, or dried soup base samples. If these are the only RTE products, then when you receive a sample request, mark code 53 in block 33, make a note on which products are produced, and return the 10,210-3 to the lab. If OPHS decides to sample these products, a special note is printed in block 18 of the sample request form.

Plants are put into projects by OPHS. Remember, there are 4 types of verification testing: Intensified, Targeted, Low-targeted and Non-targeted.

Here is an example of what may be in block 18.

Block 18 – Additional Instructions

* See FSIS Directives 10,240.3 (12/09/02) and 10,210.1 amend. 5 for instructions on this sampling program.
* Collect a RTE sample other than Non-Targeted as defined in FSIS Directive 10,240.3, giving priority to high and medium risk products. If the establishment produces ONLY Non-Targeted type products, DO NOT COLLECT A SAMPLE, mark the appropriate box in block 28, and mail the form to the lab in block 9.
* To be analyzed for: Listeria monocytogenes AND Salmonella. If fully cooked meat patties (318.23), or dry or semidry fermented sausage, also E. coli O157:H7.
* Complete all info requested in blocks 19, 20, 22 & 28-32. Enter NA in any required block where the info is not applicable or not available. DO NOT LEAVE REQUIRED BLOCKS BLANK. The lab cannot analyze samples with incomplete forms

If you have a choice of several products, pick high or medium risk products first. If the plant does not make a RTE product assigned a risk, then collect any other RTE product, except the non-targeted group of products which are listed in FSIS Directive 10,240.3.

If you think that the plant should be in a different testing program, contact your front line supervisor to coordinate it through the District Office.

Follow the normal sampling steps that you would for any sampling. For RTE product samples, you have additional information you must supply to the lab in block 28. Here is an example of what type of information you may need to supply.

Block 28 – Remarks

Product Name:_____ Production Date: _____ Date or Lot Code: _____
Check if intact sample is short weighted/slack-filled ___ Time of collection: _____(HHMM)
If sausage, is it dry or semidry fermented sausage? ____yes ____no
This sample is: _____ (1) Targeted _____ (2) Low-Targeted

This establishment produces products that are (check all that apply):
____ (1) Targeted _____ (2) Low-Targeted _____ (3) Non-Targeted

Establishment Contact Person: _____ Phone No. _____

***NOTE**:* In order to collect the appropriate product sample as well as completing the information in block 28, you must determine in which sampling program products fall. You should use FSIS Directive 10,240.3 to help you make appropriate decisions.

1.) Decide if the plant makes high/medium or low risk product.
2.) Decide if the plant has a science-based program (yes or no).
3.) If the plant does have a science-based program, determine if it is sharing data with FSIS (yes or no).

BONUS WORKSHOP

Use the Flowchart: Determining Testing Verification Program. Place each product listed here into a verification testing program. All products are produced by plants with science-based programs to address the growth of *Lm* and all plants share their data.

1. Roast beef
2. Frozen meatballs
3. Lunchmeat
4. Beef jerky
5. Bone-in honey cured ham
6. Knockwurst
7. Meatballs
8. Fried chicken
9. Pork BBQ
10. Dry-cured ham
11. Frankfurters
12. Frozen chicken nuggets

Information to consider when doing the workshop
Those products that have a risk assigned to them start out in the intensified sampling program. If they have a science-based program, ***AND*** they share the results with FSIS, they "drop" to the targeted category. If they produce product that falls into the low risk category (see page 4 of the Directive) ***AND*** share their science-based program results, they drop to the low-targeted sampling program.

If they produce low-targeted product and have a science-based program and do NOT share their results with FSIS, they go back to the targeted sampling program.

All "other" RTE products currently are not assigned a risk. These can fall into either the targeted or low-targeted sampling frame. They get categorized regardless of whether they have a science-based program or not. (The science-based program is not a factor for these plants.) They will be either targeted or low-targeted.

If a plant is eligible for intensified sampling, the IIC should notify the District Office under the following conditions that the plant

- produced a high risk product,
- has no science-based program,
- has construction in the RTE area,
- has multiple sanitation problems in the RTE area,
- has multiple positive *Lm* results (from either FSIS or plant testing program), or
- fails to take corrective action for *Lm* positives.

If a product surface tests positive for *Lm*, all product from the lot that contacted that surface is considered adulterated. (This assumes that there is testing for each lot, and that if there is a positive for *Lm*, there is a clean up before any other lot is produced. If this is not the case, all product produced between the positive *Lm* sample and a negative *Lm* sample would be considered adulterated.)

Step 2: Notify Plant Management

Plant management must be notified whenever a sample is going to be taken. This gives management the option of holding the product represented by the sample pending test results. Since the plant may opt to hold the lot, it needs sufficient time to make the necessary arrangements to do so. You should discuss the notification and timeframes with plant management ***prior*** to any sample requests being received in order to have an agreed upon protocol for notification in place when a sample must be collected. In some cases, you must inform the plant a number of hours or even days in advance, such as those plants operating under an extended clean-up or because of the production process involved (dry fermented sausages, etc.). Once you have determined the lot to be sampled, the sample collection must be done randomly. That is, every unit in that lot should have an equal opportunity of being selected.

In the case of RTE products, you must give plant management a handout stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial analyses results. (See Attachment 1.) This handout can be used at a weekly plant meeting to discuss these issues with plant management so they are aware of the procedure and protocol you will follow.

Step 3: Collect the Sample

If possible, collect the sample from the current day's production that has passed the pre-shipment review. However, the sample can be collected prior to the completion of the pre-shipment review, but the sample cannot be mailed until either the pre-shipment review has been completed or the product has been shipped[4]. If the sample is collected and held pending the pre-shipment record review, make a note of this on the sample form for the lab. This will alert the lab as to why you waited to mail the sample. If, for whatever reason, the plant decides not to ship the sampled product, but to rework it or dispose of it, then you must likewise discard the sample by returning it to the plant. Send in the 10,210-3 to the lab with an explanation of why no sample was sent (block 33, mark "other" and a short explanation). If other product is available, or will be at some time within the 30-day sampling window, it could be sampled and submitted pending pre-shipment review.

In most cases, block 4 is pre-printed with a time frame. It has a pre-printed date that tells you when to collect a sample. Usually it has a date in the "within 30 days of" section. That means that by 30 days ***after*** the date printed in the block, you should have collected a sample. Do not send in a sample after the 30 days unless you are directed to do so. If the plant does not produce the requested product in the 30-day time frame, then you will check code 72 in block 33 of the requested sample form and return the form to the lab.

[4] Product shipped without benefit of a pre-shipment review is a HACCP noncompliance.

4. COLLECT TISSUES/SAMPLES ON		
Day of:	Week of:	Within 30 days of:

Select the day to collect the sample during the time frame indicated.

All samples are selected randomly. The IIC or front line supervisor oversees sampling to ensure that different products are sampled each time sample request forms are received.

The sample must be in an intact consumer-ready package. If the sample is too large to fit into the sample container and cannot be short-weighted or slack-filled, contact the laboratory (per FSIS Notice 54-02, which is Attachment 5) to obtain a larger shipping container for the sample. If the sample does not look intact, note that in block 28.

Collect intact samples and place them into plastic bags provided by OPHS (if there is a large enough one available). The samples must be positively identified before putting them in a secure location. Identification can be accomplished by placing one of the small bar code stickers from the 5 part sample seal set[5] (7355-2A/B) on the sample and on the sample form. Samples are either kept refrigerated or frozen, depending on the instructions in the individual directives. The 5-part sample seal explained in FSIS Directive 7355.1, Rev. 2, must be used on the sample, the paperwork, and the shipping container. The Identification Label, 7355-2B, must be attached to the zip-lock bag containing the sample and the 10,210-3 sample form.

If the lab receives an insufficient amount of product to perform all of the specified analyses, or the sample is not collected within the designated time frame on the collection form (e.g., Day of, Week of, Within 30 days of, which is 30 days after the date printed in block 4) the sample is discarded (see Attachment 3 for discard reasons).

[5] These (FSIS Form 7355-2) replace the green 7355-1 seals. These seals use bar codes for tracking and matching samples and forms.

Step 4: Complete the Form and Package and Mail the Sample
When you receive a sample request, review it. Especially note the information printed in key blocks.

Key blocks are

Block 9: Name & receiving laboratory – Filled in by laboratory; you should check the shipping container to see if the right address is on the shipping container.

Block 14: Project number

Block 18: Additional instructions - Read carefully to find out what sample needs to be taken for RTE sampling.

Block 19: Date collected - Enter the date you collected the sample. Check block 4 to make sure this date is after the date printed in block 4, but no more than 29 days after that date.

Block 20: Date sent to lab - Enter the date you mailed the sample.

Block 22: Product held – Check the "yes" box if the sampled/affected product was held, or check the "no" box if the establishment did not hold the product.

Block 28: Remarks – You must

- Provide product name, production code, date or lot code.
- Provide the time of sample collection (hour and minute).
- Indicate if the intact sample is short-weighted/slacked-filled.
- Indicate if the sample is dry or semi-dry fermented sausage.
- Indicate if the sample is targeted or low-targeted product.
- Indicate if the establishment produces products that are Intensified/ Targeted/Low-Targeted.
- Provide the name of the establishment contact person and phone number.
- Make a note that "This is an intact sample" if the sample does not appear intact.

Block 29: Collector's signature – Sign your signature.

Block 30: Name of collector – Print your name.

Block 31: Badge number – Put your badge number here. This identification is necessary for a traceable chain of custody if the Agency has to take the establishment to court based on the FSIS laboratory results.

Block 32: Telephone number at the establishment – Provide the telephone number where you can be reached at the establishment.

It is vital to include the ***completed*** paperwork. If the paperwork is not complete, or if it is missing or for the wrong product sample, the sample ***will*** be discarded. The sample seal/sticker numbers all have to match, except if there are multiple samples, then the seal on the outside container only has to match one sample. ***All*** sample forms received ***without*** a collection date are discarded.

Microbiological pathogen samples submitted on FSIS Form 10,210-3 must have Part II, blocks 19, 20, 22, and 28-32 completed. Otherwise the lab discards them. A list of discard reasons is in Attachment 3.

19. DATE COLLECTED	20.DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO

29. COLLECTOR'S SIGNATURE	30. *NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

Note: *The badge number is necessary for positive identification for a traceable chain of custody. For example, if there are two Sam Smiths in FSIS, it is important to identify which Sam Smith sent the sample. Using your badge number does not violate your privacy, but it does supply the necessary positive identification for legal purposes.*

Another Bonus Workshop

Using the following information, fill out the attached form. Products produced at this establishment are roast beef, beef jerky, and chicken nugget fritters that are sold unfrozen and frozen. Read the form. What sample will you collect? Complete the requested information using today's date for collecting and mailing the sample, and make up a lot number.

Internal lab code here	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **REQUESTED SAMPLE PROGRAMS** ☐ FOOD CEMISTRY ☐ MICROBIOLOGY ☐ RESIDUE	*Barcode here* 1. SAMPLE FORM NO.

PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS

2. SAMPLE TYPE CODE	3. EST. NO.	4. COLLECT TISSUES/SAMPLES ON			5. REGION/ DISTRICT	6 STATE	7. CIRCUIT/IFO
		Day of:	Week of:	Wthin 30 days of:			

8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est.,Retail Store)	9. NAME & ADDRESS OF RECEIVING LABOATORY

10. SLAUGHTER CLASS CODE	11. SPECIES TO COLLECT	12. TISSUE	13. ANALYSIS REQUESTED

14. PROJECT NO.	15. COUNTRY OF ORIGIN	16. COUNTRY COPY	17. FOREIGN EST. NO.

18. ADDITIONAL INSTRUCTIONS

PART II. COLLECT SAMPLE INFORMATION (To be compluted by sample collector)

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO
23. FSIS N9540-1 NO.	24. LOT NO.	25. IMPORTS ☐ NORMAL (06) ☐ INCREASED (07) ☐ SPECIAL (53) ☐ HOLD (24)	

26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE	*27. ANIMAL ID (Tag No.)*

28. REMARKS

29. COLLECTOR'S SIGNATURE	*30. NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ *REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)*

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS *(If checked, plant will be removed from this sampling program)*

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ *OTHER (Explain)*

PART III, LABORATORY RECEIPT INFORMATION

34. SAMPLE PACKAGING ☐ 3034 Intact Package ☐ 3035 Non-intact Package	35. SAMPLE RECEIPT DATE

36. PRODUCT CODE	37. NO. SAMPLES IN COMPOSITE	38. SAMPLE RECEIPT TEMPERTURE

39. SAMPLE RECEIPT CONDITION CODE	40. SEAL CONDITION CODE	41. DISCARD CONDITION CODE

FSIS FORM 10,210-3(3/97)

Samples should be shipped in FSIS-furnished containers, unless special arrangements are made with the lab. The ***proper*** paperwork (properly ***completed***) and labels must accompany **each** sample.

Only one sample should be in a shipping container to avoid confusion. But the laboratory does not discard a sample just because two different samples are in the same shipper. They will discard them if it is not clear which sample goes with which sample form. They will also discard the sample if you mail it to the wrong lab. For this reason, you must double-check and compare the address on the FedEx air-bill to make sure it is going to the lab indicated in block 9 of the sample form. Directions for sealing samples are in FSIS Directive 7355.1, Rev. 2.

The shipping containers you use should have the top and bottom sealed by the lab with red and black striped tamper-evident tape. If you have shipping containers on hand that the lab has not recently sent to you, you may still use them, but you need to apply a second FSIS Form 7355-2A to the bottom with an explanation written on it. This is only to be done during a limited grace period to use the shippers that you had prior to the lab using the tape. You will ***not*** receive any tamper-evident tape to use.

When multiple immediate containers are used for a single sample, all of those containers must be mailed in the same shipper. Example, if two pounds of product are needed, and the product is packaged in 6 oz packages, then 6 packages must be shipped (36 oz total) to at least equal 2 pounds (32 oz). Do not overfill the box. All the samples should go in the same bag or a larger bag should be requested as described in FSIS Notice 54-02 (Attachment 5).

Pack the sample in this order.

1. Freeze pack
2. Coolboard
3. Zip-lock bag containing the sample with bar code sticker and sample form containing a bar code sticker (The zip-lock bag bears the 7355-2B, Identification Label)
4. Extra little bar code sticker that was not used
5. Foam plug
6. Closed shipper with Container Seal (7355-2A)

A frozen freeze pack must be added for product that was stored refrigerated or frozen. Shelf stable products should also contain the freeze pack to ensure that the product does not get over-heated during shipping. The piece of cardboard, called the coolboard, goes on top of the freeze pack to separate the freeze pack from the sample. The bagged sample is put into a larger bag along with its corresponding paperwork, labeled for identification purposes with FSIS Form 7355-2B and then put into the shipper.

In most cases, filler material is ***not allowed*** in the shipping container. This means that no newspaper, paper towels, etc., can be inside the shipping container to take up any empty space. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper. However, some types of RTE containers are not very durable and are prone to leakage. The primary examples are plastic tubs and aluminum trays. When these containers are bounced around inside a shipper, along with a frozen freeze pack, they may crack or burst. In such cases as these, it is acceptable for you to put in some extra packing material around the sample container to act as a cushion between the container and the sides of the shipper. Then push the foam plug down firmly. The goal is to prevent the sample container from bouncing around inside the shipper.

Any unused bar coded stickers need to go into the shipper with the sample. This insures that it won't accidentally get used on another sample, as well as allows the lab to account for all 5 parts of the 7355-2 (the Container Seal, Identification Label, and 3 little bar code stickers).

FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal. This further adds to the sample integrity. The 7355-2A is stronger than 7355-2B, FSIS Laboratory Sample Identification Label, and does not tear easily. It was made specifically for the purpose of sealing the shipping container. The Identification Label is not as durable and may tear if you are not careful when you apply it to the bag containing the sample and the sample form.

Samples are mailed so they arrive at the lab the next day. Samples should not be held over the weekend if it is avoidable (not more than three days). However, if a sample must be held over the weekend (Friday to Monday), it must be refrigerated or frozen, depending on the directive instructions. The current contract carrier will ***deliver*** on Saturdays, but not ***pick-up***. A "Saturday Delivery" label must be used. Put a checkmark (√) in the "Saturday Delivery" portion of the delivery airbill or stamp.

FSIS Laboratories

There are three FSIS Field Service Laboratories. The Eastern lab is in Athens, GA, the Midwest lab is in St. Louis, MO, and the Western lab is in Alameda, CA.

The FSIS labs are responsible for providing the sampling supplies. Whenever supplies are needed, e-mail a request through Outlook following FSIS Notice 54-02 (see Attachment 5).

Step 5: React to Results

Access LEARN to track your sample receipt and results. LEARN means Laboratory Electronic Application for Results Notification. More information is contained in FSIS Directive 10,200.1. LEARN is a computer application that notifies FSIS personnel and establishment management of the receipt and status of samples sent to the FSIS analytical laboratories for testing. LEARN reports when a sample was received at the lab, if it was discarded and the reason for the discard, and the results of the analysis when it is completed.

If you click on the correct sample in LEARN, at the bottom of the screen there should be a discard reason/description. This is below the normal area on the screen where results are found.

When a sample is submitted for analysis, you must check LEARN the following day to see that the sample was received and was not discarded. Access LEARN on your FAIM computer. After logging onto the Intranet, you can view a 28-day history of sampling for an individual establishment by going to the following address.

http://dchqintra/learn/estindex1.cfm

The web address listed above is used to connect to LEARN. When you go to the LEARN address, you have three options.

1. Enter the form number,
2. Enter a single establishment number to obtain all the results in the database for that establishment, or
3. Go to a customizable list of samples for all establishments in a circuit.

Option 3 is particularly useful if you have a patrol assignment, since you can see the status of the samples of all the establishments you are responsible for at one time, on one screen, without having to type in several different individual establishment numbers as in Option 1. You can narrow the information to show just a particular type of sample.

Click on “Submit”. You will then see the collection date and form number and whether the sample was “Received” or “Not Analyzed”. Once the analyses are complete, the results are posted in the results column.

Microbial analyses results are reported as positive or negative. Some are listed as presumptive positive.[6] LEARN provides immediate notification of presumptive

[6] Evidence is there to suggest the product is out of compliance, but additional analyses and/or samples are needed to **confirm** it.

positive RTE samples. Results are available as soon as the analysis is complete. OPHS e-mails sample results to plants that complete FSIS Form 10,230-2, FSIS Establishment E-mail (Internet) Address Collection Form, and submit it to OPHS. You are responsible for providing results to the plant, even when OPHS e-mails results to the plant.

Turnaround Time for Positive and Negative Results

Analysis	Minimum[7] Number of Days from Receipt When the Result Is	
	Negative	Positive
Salmonella	1	5
Listeria monocytogenes	3	6
E. coli O157:H7	1	4

Presumptive Positive
When there is a presumptive positive (posted in LEARN), notify plant management that the sample was presumptive positive. Inform the plant that if the result is confirmed positive, it will need to account for all affected product (as with any positive analyses of a pathogen on RTE products).

Positive
Positive results are also on the LEARN system. You are responsible for obtaining these results and notifying the plant. The DO only alerts the plant in cases where the lab notifies[8] the DO (prior to posting the information in LEARN) due to a presumptive/potential positive. This contact ensures that the plant receives this important message if you are not available. It is key for you to check LEARN on a daily basis.

Plant management must account for all affected products by identifying them and their locations. The plant is expected to take the proper corrective and preventive measures (§417.3(a) or (b)). It may need to conduct a reassessment of its HACCP plan and/or reevaluate its SSOP or prerequisite programs.

These corrective and preventive measures may be in the HACCP plan already. The plant may claim that the organism testing positive is an unforeseen hazard, in which case the corrective actions should be taken as per §417.3(b). Since

[7] The term “minimum” is based on analyses that do not encounter any difficulties. If a sample presents any difficulties, additional purification efforts may extend the time by 1 to 4 days. Particularly problematic samples may need to be sent for isolation to the Microbiological Outbreak and Special Projects lab for DNA testing prior to reporting a result.

[8] The lab uses BITES (Biological Information Transfer E-mail System) to notify the DO.

RTE products contaminated with *Listeria monocytogenes* and *Salmonella* have recently been implicated in food borne illnesses, you may want to review the hazard analysis to determine whether the plant has justification or supporting documentation for the decision not to identify these hazards as reasonably likely to occur. Plants are expected to recall any affected product that has left the plant's immediate control (i.e., been distributed in commerce).

Specific actions you follow as a result of a RTE product testing positive for a pathogen are provided in the Documentation and Enforcement module.

Rework

The plant may use product that tested positive for a pathogen as rework, or it may destroy the product. If the plant uses the product as rework, it should be addressed in the HACCP plan. The plan must address any hazards presented by the practice, such as the potential hazard of increased bacterial tolerance to survive a "kill" step if the rework is a cooked product.

If the plant uses product that tested positive as rework, then critical limits and critical control points need to account for any potential added hazards. When product that tested positive is identified, it may be shipped to a federally inspected facility for further processing (e.g., recooked). It must be transported under FSIS Form 7350-1, Request and Notice of Shipment of MPI Sealed Meat/Poultry. That second establishment must address the rework issue in its HACCP plan.

If the practice is done occasionally, the plan may only need to address the procedures, critical limits, and critical control points to meet when lots containing rework, from product that tested positive, are processed.

Summary

Procedure 05B02 is devoted to directed sampling for food safety concerns. Currently, microbiological hazards are of most concern in RTE products, so FSIS is focusing on analyses for *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7.

Process verification samples are selected when directed by the Procedure Schedule or Agency programs. They are randomly taken to ensure that the establishment is maintaining a process that produces product in compliance with regulatory requirements. Additional sampling may occur when a routine sample is positive or a plant may be placed into the Intensified Verification Testing Program. This type of sampling is used to verify the effectiveness of the plant's corrective and preventive measures taken according to its HACCP plan.

Noncompliant sample results may trigger additional sampling. It is very important that you carefully read all the printed material on the form when you receive it to ensure appropriate sampling. The form usually makes reference to specific directives that provide information related to the directed sampling activity.

FSIS Directive 10,240.3 combines product testing with environmental testing to gain an overall picture of the effectiveness of the plant's food safety system concerning *Listeria monocytogenes* (*Lm*) specifically.

FSIS expects all RTE products to be handled in sanitary environments. There are special concerns about handling and the environment when RTE products have post-lethality exposure in the plant. Plants producing such products are expected to address the product handling, food contact surface sanitation, and environmental issues. However, FSIS will not focus its verification efforts on "other" RTE products and their expected control programs at this time. This does not mean that FSIS will not conduct verification testing in these plants. FSIS will conduct verification testing at these plants but, for the most part, will collect only one product sample at a time. Currently, FSIS does not automatically consider conducting intensified verification testing of any of these "other" RTE products unless there is cause. The same holds true for RTE products that are not exposed post-lethality. Each plant must determine its own sanitation control measures needed to produce RTE products. Plants may choose to address environmental sampling in HACCP plans, SSOPs, prerequisite programs, GMPs, or not at all.

The intensity for verification testing for *Lm* is determined by the design of the plant HACCP plans, SSOPs, or other prerequisite programs. If any RTE product sample or food contact surface sample tests positive for *Lm*, FSIS expects the plant to take corrective and preventive measures to ensure that the pathogen

does not recur in the product and that the plant will prevent adulterated product from entering commerce.

Keep in mind that end-product testing assumes that if the organism is in the product, it will be in the product that you selected for your sample. However, the truth is that it may be on product, but not on the sample. Also, just because *Lm* is not found as a result of environmental testing, it does not mean that *Lm* is not in the plant. All testing programs have their limitations, but overall, a sound testing program can add to assuring public health whereas no testing program falls short of public expectations. Testing programs are just one part of an integrated approach to a good food safety program.

As new technologies and methods of producing products are developed, and as new pathogens emerge that affect meat and poultry food safety, FSIS will adjust its efforts to continue being a public health agency. New or different microorganisms may be added to the list of those for which the Agency currently tests. It will continue to be the responsibility of the in-plant inspection force to verify that establishments meet their food safety obligations.

Workshop II

1. When would a Dutch loaf sample be sent to the lab for a *Listeria monocytogenes* directed sample?

    a. the day before the “use by” date
    b. just prior to packaging
    c. the first day FedEx is available after the pre-shipment review is completed
    d. as soon as the lot is assembled

2. Plant management must be notified of pending sample collection

    a. when you receive the analysis result (either from LEARN or the DO).
    b. after pre-shipment review has been completed.
    c. enough in advance to allow the plant to hold the product, but not soon enough to allow it to alter the process.
    d. because of the Freedom of Information Act (FOIA).

3. How many samples should be submitted per shipping container?

    a. 1
    b. 2
    c. 3
    d. 4

4. If a sample is too large for the shipping container, you

    a. have the plant use a different package to enclose the product.
    b. contact the FSIS lab for a larger shipping container.
    c. select a different product produced under the same HACCP plan.
    d. contact the ADME.

5. If a plant delivered product from a sampled lot to a customer, but retrieved all of it before the report of the FSIS sample result, is the product deemed to have been shipped?

    a. YES
    b. NO

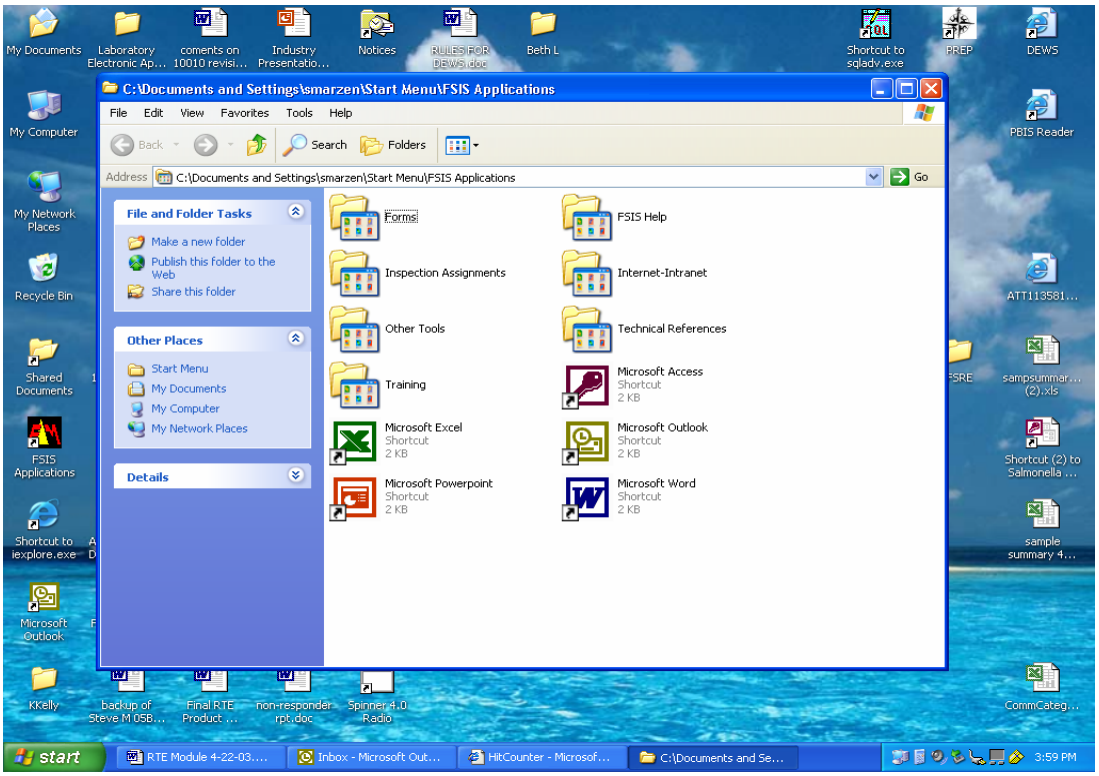
Justify your answer.

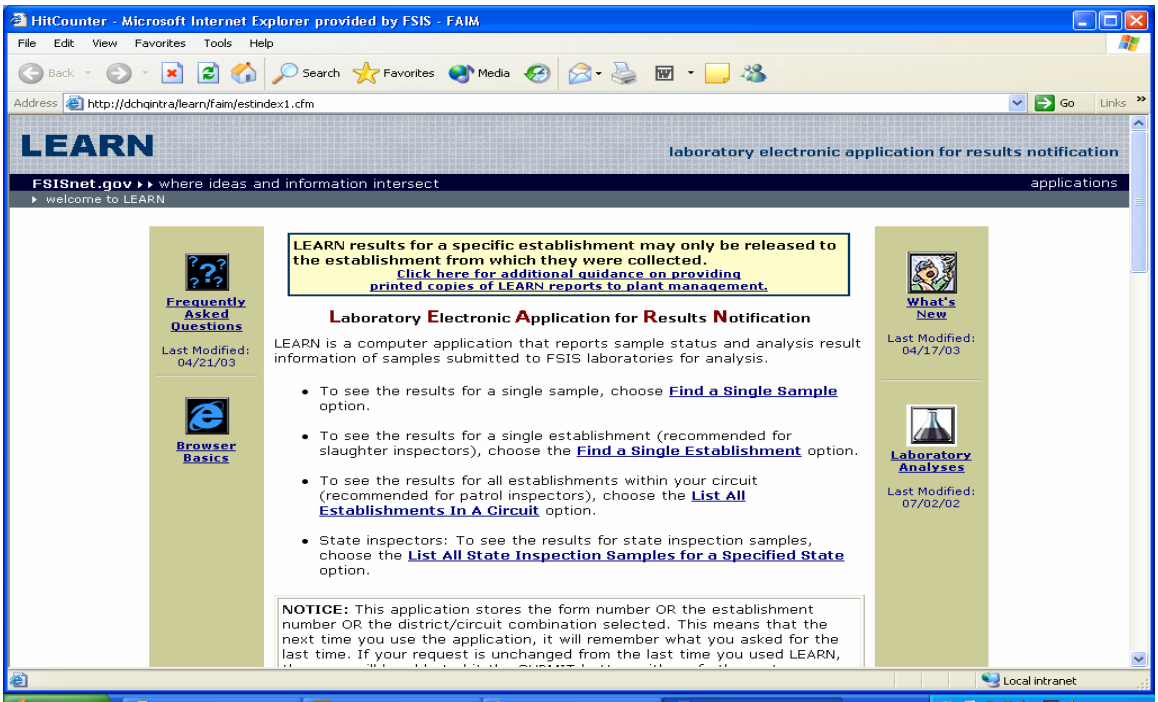
Matching

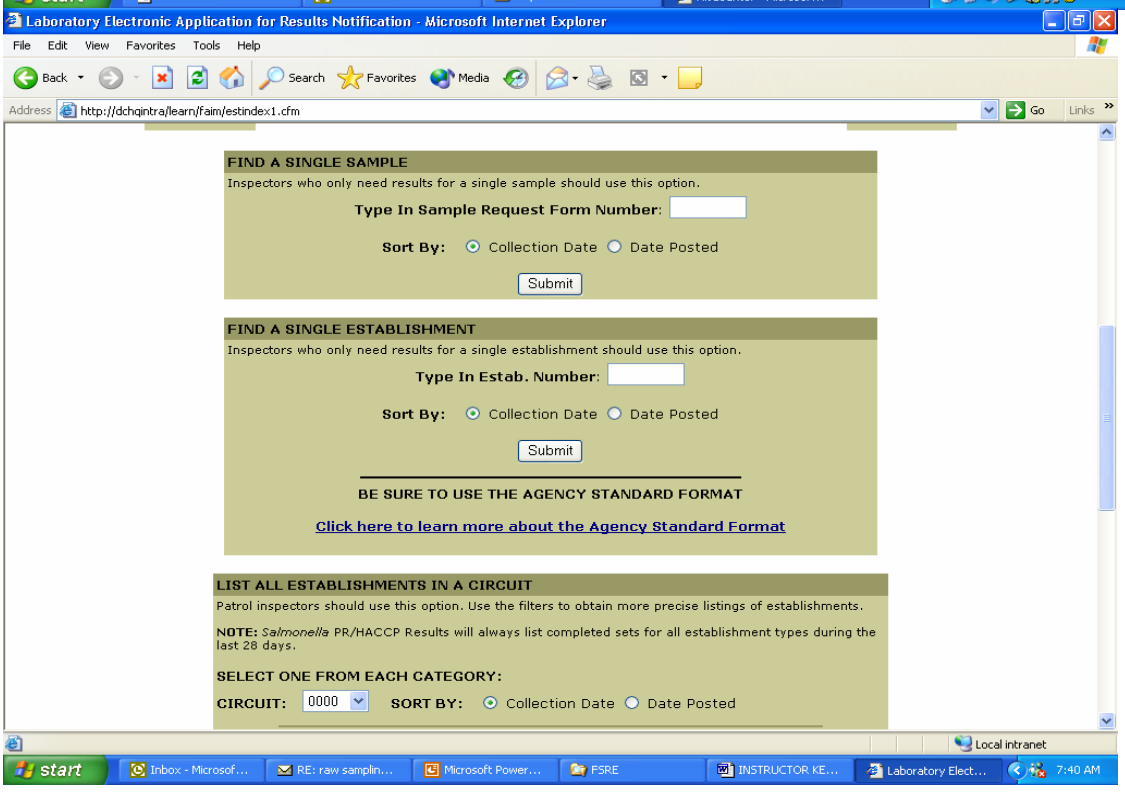
Definitions	Answers
__ Sampling initiated by OPHS	A. Affected
__ A check to determine that a system is working as intended	B. Aseptic
__ A sample in its final packaged form	C. Directed
__ An individual package or container	D. Intact
__ Product representing a sampled lot, as well as product produced in the same time frame between complete clean-ups	E. RTE
__ Not adding pathogenic organisms	F. Recall
__ A collection of product that represents a larger group	G. Retain
__ The amount of product represented by a sample	H. Sample
__ Product is placed under official control in the plant	I. Sampled Lot
__ A plant's voluntary removal of product from commerce	J. Sample unit
__ Product intended to be consumed without any further safety preparation steps	K. Verification

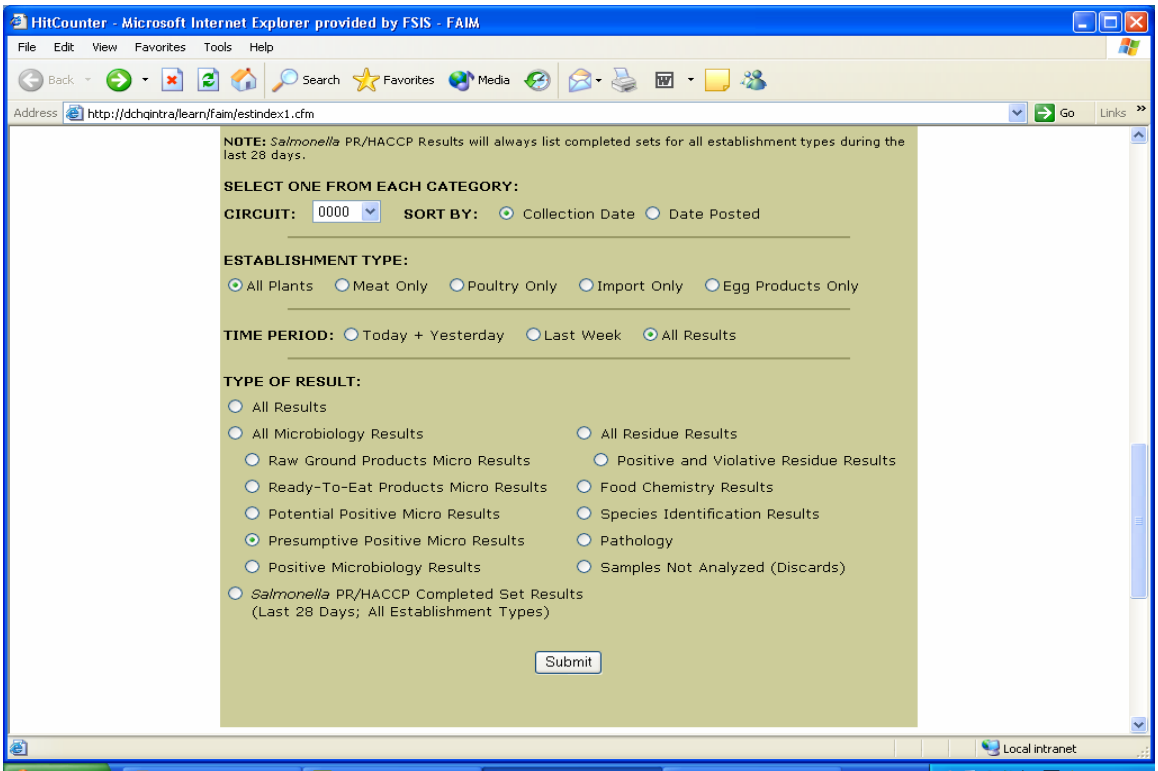
Appendix

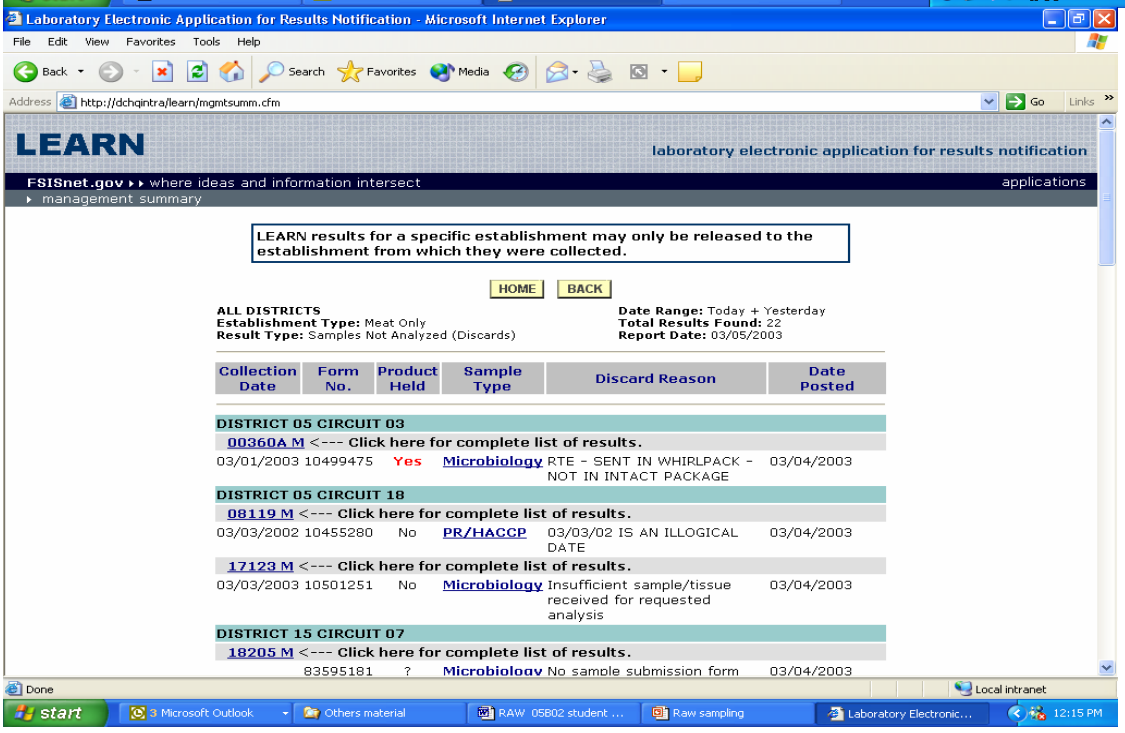
LEARN Screens from the Power Point Presentation




HitCounter - Microsoft Internet Explorer provided by FSIS - FAIM
File Edit View Favorites Tools Help
Address http://dchqintra/learn/faim/estindex1.cfm
LEARN
laboratory electronic application for results notification
FSISnet.gov ▸▸ where ideas and information intersect
applications
▸ welcome to LEARN
Frequently Asked Questions
Last Modified: 04/21/03
Browser Basics
LEARN results for a specific establishment may only be released to the establishment from which they were collected.
Click here for additional guidance on providing printed copies of LEARN reports to plant management.
Laboratory Electronic Application for Results Notification
LEARN is a computer application that reports sample status and analysis result information of samples submitted to FSIS laboratories for analysis.
To see the results for a single sample, choose Find a Single Sample option.
To see the results for a single establishment (recommended for slaughter inspectors), choose the Find a Single Establishment option.
To see the results for all establishments within your circuit (recommended for patrol inspectors), choose the List All Establishments In A Circuit option.
State inspectors: To see the results for state inspection samples, choose the List All State Inspection Samples for a Specified State option.
NOTICE: This application stores the form number OR the establishment number OR the district/circuit combination selected. This means that the next time you use the application, it will remember what you asked for the last time. If your request is unchanged from the last time you used LEARN,
What's New
Last Modified: 04/17/03
Laboratory Analyses
Last Modified: 07/02/02
Local intranet
start
RTE Module 4-22-03....
Inbox - Microsoft Out...
C:\Documents and Se...
HitCounter - Microsof...
3:57 PM


Laboratory Electronic Application for Results Notification - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Address http://dchqintra/learn/faim/estindex1.cfm
FIND A SINGLE SAMPLE
Inspectors who only need results for a single sample should use this option.
Type In Sample Request Form Number:
Sort By: Collection Date Date Posted
Submit
FIND A SINGLE ESTABLISHMENT
Inspectors who only need results for a single establishment should use this option.
Type In Estab. Number:
Sort By: Collection Date Date Posted
Submit
BE SURE TO USE THE AGENCY STANDARD FORMAT
Click here to learn more about the Agency Standard Format
LIST ALL ESTABLISHMENTS IN A CIRCUIT
Patrol inspectors should use this option. Use the filters to obtain more precise listings of establishments.
NOTE: Salmonella PR/HACCP Results will always list completed sets for all establishment types during the last 28 days.
SELECT ONE FROM EACH CATEGORY:
CIRCUIT: 0000
SORT BY: Collection Date Date Posted
Local intranet
start
Inbox - Microsof...
RE: raw samplin...
Microsoft Power...
FSRE
INSTRUCTOR KE...
Laboratory Elect...
7:40 AM


HitCounter - Microsoft Internet Explorer provided by FSIS - FAIM
File Edit View Favorites Tools Help
Address http://dchqintra/learn/faim/estindex1.cfm
NOTE: Salmonella PR/HACCP Results will always list completed sets for all establishment types during the last 28 days.
SELECT ONE FROM EACH CATEGORY:
CIRCUIT: 0000 SORT BY: Collection Date Date Posted
ESTABLISHMENT TYPE:
All Plants Meat Only Poultry Only Import Only Egg Products Only
TIME PERIOD: Today + Yesterday Last Week All Results
TYPE OF RESULT:
All Results
All Microbiology Results
Raw Ground Products Micro Results
Ready-To-Eat Products Micro Results
Potential Positive Micro Results
Presumptive Positive Micro Results
Positive Microbiology Results
All Residue Results
Positive and Violative Residue Results
Food Chemistry Results
Species Identification Results
Pathology
Samples Not Analyzed (Discards)
Salmonella PR/HACCP Completed Set Results (Last 28 Days; All Establishment Types)
Submit
Local intranet
start
RTE Module 4-22-03....
Inbox - Microsoft Out...
HitCounter - Microsof...
C:\Documents and Se...
4:13 PM


Laboratory Electronic Application for Results Notification - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Address http://dchqintra/learn/mgmtsumm.cfm
LEARN
laboratory electronic application for results notification
FSISnet.gov ▸▸ where ideas and information intersect
applications
management summary
LEARN results for a specific establishment may only be released to the establishment from which they were collected.
HOME BACK
ALL DISTRICTS
Establishment Type: Meat Only
Result Type: Samples Not Analyzed (Discards)
Date Range: Today + Yesterday
Total Results Found: 22
Report Date: 03/05/2003
Collection Date | Form No. | Product Held | Sample Type | Discard Reason | Date Posted
DISTRICT 05 CIRCUIT 03
00360A M <--- Click here for complete list of results.
03/01/2003 10499475 Yes Microbiology RTE - SENT IN WHIRLPACK - NOT IN INTACT PACKAGE 03/04/2003
DISTRICT 05 CIRCUIT 18
08119 M <--- Click here for complete list of results.
03/03/2002 10455280 No PR/HACCP 03/03/02 IS AN ILLOGICAL DATE 03/04/2003
17123 M <--- Click here for complete list of results.
03/03/2003 10501251 No Microbiology Insufficient sample/tissue received for requested analysis 03/04/2003
DISTRICT 15 CIRCUIT 07
18205 M <--- Click here for complete list of results.
83595181 ? Microbiology No sample submission form 03/04/2003
Done
Local intranet
start
3 Microsoft Outlook
Others material
RAW 05802 student ...
Raw sampling
Laboratory Electronic...
12:15 PM

ATTACHMENT 1

Notice to Give Plant Management When a Sample is Taken

To Establishment Manager:

X The inspector will be taking a sample of your Ready-to-Eat meat and/or poultry product or raw ground beef product to be tested for microbial hazards. Sampling is one component of verifying your HACCP system.

X To protect public health and to avoid the negative impact of a recall, FSIS strongly recommends that you hold all product represented by the sample until results are obtained.

X Most negative results are available within 3 days; confirmed positive results may take up to 8 days. Results will be provided to you be the inspector or the District Office. For results of future samples, you can receive results by e-mail (contact your District Office for a copy of FSIS Form 10,230-2).

X If a recall is needed, FSIS expects you to initiate the recall in a timely fashion—usually the same day. See FSIS Directive 8080.1 for further details.

X It is your responsibility to determine the amount of product represented by the sample. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. See FSIS Directives 10,240.2 Rev. 1 and 10,010.1.

X If a test result is positive, and you have distributed the product, FSIS will request that you conduct a recall. FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

ATTACHMENT 2

Resources

Currently, there are several directives associated with microbial sampling of RTE products that fall into the 03E, 03F, 03G, and 03I process categories. This list is current as of 1/03. Each PE should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently. The Outlook Folder (Public Folders ➜ All Public Folders ➜ Agency Issuances ➜ Directives or Indexes and Checklists) has a listing of the current directives (and any revisions, etc.). The actual directives are posted under the Directives Folder. New listings may also be posted in LEARN on the "What's New" page.

Selected FSIS Sampling References for RTE (03E, 03F, 03G, and 03I)		
FSIS Directive Number	**Directive Title**	**Directive Date**
5000.1	Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations	
7355.1, Rev 2	Use of Sample Seals for Laboratory Samples and Other Applications	12/3/02
8080.1, Rev 3	Recall of Meat and Poultry Products	1/19/00
10,200.1	Accessing Laboratory Sample Information via LEARN	7/19/01
10,210.1, Amend 5	Unified Sampling Form	2/11/03
10,230.1	Species Identification Sampling for Cooked Product	10/14/87
10,230.2, Amend 1	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses	9/4/92
10,240.3	Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program	12/9/02
10,600.1	Sample Shipment Procedures	10/6/83

The 10,210-3, Sampling Frame Update Form (FSIS Directive 10,230.3, Rev 1), is no longer necessary to fill out. The PBIS 5 captures the information that OPHS needs in order to send out appropriate sample requests to the appropriate establishments.

ATTACHMENT 3 Discard Reasons

These discard reasons cover all samples, NRTE/RTE and raw. The codes are not given in this table since they are used for tracking purposes. Your frontline supervisor has access to this information and monitors the number of discarded samples. This table includes all the discard reasons. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

COLLECTED SAMPLES/NOT ANALYZED	***FORMS WITH NO SAMPLE COLLECTED***
RTE-Low Targeted Product-Sample Submitted in Error	Freezer Problem in Plant
RTE-Non-Targeted Product-Sample Submitted in Error	Sample/Form Missent
No Sample Received with Form	Other Inspector/Plant Problems
RTE-Low & Non-Targeted Prod-Sample Submit. in Error	No Plant Freezer
Collected Outside Scheduled Time Frame	Plant Has It's Own Testing Program
Temperature Too High	Required Sampling-Plant With Own Testing Program
Tissue/Sample Spoiled/Rancid	RTE-Low Targeted Products Plant
Container Damaged	RTE-Non-Targeted Products Plant
Commingled Tissues	RTE-Low & Non-Targeted Products Plant
No Identification on Tissues	Requested Product not Produced
Wrong Tissue/Sample for Requested Analysis	Inspector Error
Insufficient Tissue or Sample	No Reason Given by Inspector
Delayed Shipment	Inspector Not Following Instructions
Shipped on Friday w/o Saturday Delivery label	Insufficient Time to Collect Sample
Sample Forwarded to Another Lab	District Office Problem/Error
Original Form Not Submitted w/Sample	No Container/Supplies Available
Target Tissue Not Received	Form Arrived Too Late
No Form Received with Sample	Inspection Withdrawn
Original Form Altered by Sample Submitter	Inspection Suspended Officially
Plant Has It's Own Testing Program-Sample Submitted	Plant Closed/No Kill
Laboratory Problem*	Species Not Available
No Freeze Packs/Coolants in Sample Box	Collection Cancelled by Headquarters/TSC/ DO
Sample Container Leaking	Coding Error on Form
Collection Date Not Day Prior to Sample Receipt	
Cooked Product	
E. coli Ground Product Held Too Long Before Shipping	
Excessive Fat	
Ground Prod Sample Held>3 Days Before Shipping	
Sent to Wrong Lab	
Sample ID # on Bag does not match ID # on Form	
Non-Intact Sample Package	
Raw Product Submitted for RTE program	
Security Seal Missing or Not Intact	
Temperature Too Low	
No Accredited Lab Tests Performed	
Headquarters/ TSC/DO Discard	
Sampling Instructions Not Followed	

ATTACHMENT 4

Internal lab code here	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **REQUESTED SAMPLE PROGRAMS** ☐ FOOD CEMISTRY ☐ MICROBIOLOGY ☐ RESIDUE	*Barcode here* 1. SAMPLE FORM NO.

PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS

2. SAMPLE TYPE CODE	3. EST. NO.	4. COLLECT TISSUES/SAMPLES ON			5. REGION/ DISTRICT	6 STATE	7. CIRCUIT/IFO
		Day of:	Week of:	Wthin 30 days of:			

8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est.,Retail Store)	9. NAME & ADDRESS OF RECEIVING LABOATORY

10. SLAUGHTER CLASS CODE	11. SPECIES TO COLLECT	12. TISSUE	13. ANALYSIS REQUESTED

14. PROJECT NO.	15. COUNTRY OF ORIGIN	16. COUNTRY COPY	17. FOREIGN EST. NO.

18. ADDITIONAL INSTRUCTIONS

PART II. COLLECT SAMPLE INFORMATION (To be compluted by sample collector)

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO

23. FSIS N9540-1 NO.	24. LOT NO.	25. IMPORTS ☐ NORMAL (06) ☐ INCREASED (07) ☐ SPECIAL (53) ☐ HOLD (24)

26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE	*27. ANIMAL ID (Tag No.)*

28. REMARKS

29. COLLECTOR'S SIGNATURE	*30. NAME OF COLLECTOR (Print)*	31. BADGE NO.	32. TELEPHONE NO. AT EST.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ *REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)*

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS *(If checked, plant will be removed from this sampling program)*

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ *OTHER (Explain)*

PART III, LABORATORY RECEIPT INFORMATION

34. SAMPLE PACKAGING ☐ 3034 Intact Package ☐ 3035 Non-intact Package		35. SAMPLE RECEIPT DATE

36. PRODUCT CODE	37. NO. SAMPLES IN COMPOSITE	38. SAMPLE RECEIPT TEMPERTURE

39. SAMPLE RECEIPT CONDITION CODE	40. SEAL CONDITION CODE	41. DISCARD CONDITION CODE

FSIS FORM 10,210-3(3/97)

ATTACHMENT 5

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	54-02	12/2/2002

Requesting Sample Collection Supplies

Effective February 1, 2003, the toll-free lab supply hotline (1-877-709-1982) will be replaced by the following Outlook email addresses:

Sampling Supplies – Eastern Laboratory
Sampling Supplies – Midwestern Laboratory
Sampling Supplies – Western Laboratory
Sampling Forms - Headquarters

If you need sample collection supplies, email the laboratory designated on your sample request form, or the lab to which you will be sending the sample (see FSIS Notice 18-02 and/or LEARN). In order for the lab to promptly respond, the message must contain:

- establishment number
- daytime phone number
- project identification (if applicable)
- supplies needed

If a daytime phone number is not available, the laboratory may need to reply by email. Supplies will be sent via FedEx to the Overnight Mail address in the PBIS database for this establishment.

If you need additional copies of FSIS Form 10,210-7 to complete a *Salmonella* sampling set, send an Outlook message to Sampling Forms – Headquarters. Directed sample requests on FSIS Form 10,210-3 cannot be regenerated if lost. All other FSIS sample forms (i.e., 10,600-1) should be ordered through the regular FSIS Field Supply system at Beltsville (1-800-714-8335).

The above Outlook addresses may be used immediately upon receipt of this notice. After February 1, 2003, the toll-free phone line will no longer be an active working number, so the Outlook addresses must be used.

DISTRIBUTION: Inspection Offices;T/A Inspectors;Plant Mgt;T/A Plant Mgt;TRA;TSC;Compliance officers;FSIS Laboratories;Import Offices	NOTICE EXPIRES: 12/1/2003	OPI: OPPD

What if I cannot access Outlook?

State inspectors without FAIM computers, should contact their state coordinators, who will email the following addresses from outside the FSIS Exchange server:

SamplingSupplies-EasternLab@fsis.usda.gov
SamplingSupplies-MidwesternLab@fsis.usda.gov
SamplingSupplies-WesternLab@fsis.usda.gov

The District Inspection Coordinator may also be contacted to assist inspection program personnel without FAIM computers to send emails to the appropriate Outlook mailbox.

Direct questions regarding these procedures to the Technical Service Center.

Philip S. Derfler **/s/**

Deputy Administrator
Office of Policy and Program Development

ATTACHMENT 6

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS DIRECTIVE	10,240.3	12/9/2002

MICROBIAL SAMPLING OF READY-TO-EAT (RTE) PRODUCTS FOR THE FSIS VERIFICATION TESTING PROGRAM

PART 1 - GENERAL

I. PURPOSE

This directive provides inspection program personnel with instructions for when to sample ready-to-eat (RTE) meat and poultry products produced in official establishments as one aspect of the verification activities conducted by FSIS. **Part 1** provides the purpose, cancellation, references, reason for reissuance and terminology. **Part 2** outlines the type of verification testing FSIS will conduct in establishments, depending upon the risk of the product and operation. **Part 3** outlines the sample collection procedures and the regulatory actions that FSIS will follow should a sample of product test positive for a microbial hazard, including *Listeria monocytogenes (L. monocytogenes)*, *Salmonella*, and *Escherichia coli* O157:H7 (*E. coli* O157:H7). Part 3 also outlines new Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedure (Sanitation SOP) verification steps that FSIS will take in establishments to ensure control of *L. monocytogenes* in certain RTE products through control of their processing environments. In particular, Part 3 outlines the regulatory actions FSIS will follow should a food contact surface sample test positive for a microbial contaminant.

II. CANCELLATION

FSIS Directive 10,240.2, Revision 1, Amendment 1, dated 1/24/01

III. REASON FOR REISSUANCE

A. To clarify the procedures that are to be followed by inspection program personnel in establishments that produce certain high, medium, or low risk RTE products, particularly those products subject to exposure to the environment after the lethality step.

B. To include sampling of food contact surfaces, and sampling of other surfaces in the RTE operation, by FSIS in establishments that produce certain RTE products. Such sampling will be conducted initially by specially trained inspection program personnel, including microbiologists.

C. To provide the procedures that inspection program personnel will follow when
establishments that produce certain RTE products incorporate pathogen and indicator organism testing into their HACCP plans, Sanitation SOPs, and prerequisite programs.

IV. REFERENCES

FSIS Directive 5000.1, dated 11/21/97
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 8080.1, Revision 3, dated 1/19/00
FSIS Directive 10,200.1 dated 07/19/01
FSIS Directive 10,210.1, Amend. 3, dated 07/01/02
FSIS Directive 11,000.1, dated 1/25/00
Title 9 Code of Federal Regulations (CFR) Part 416
Title 9 CFR Part 417
Title 21 United States Code (U.S.C.) Parts 453 and 601

V. TERMINOLOGY

Environmental Samples – Samples from surfaces that have:

- indirect or potential contact with exposed RTE product in the RTE production area (e.g., mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or
- no contact with RTE product in a RTE production area (e.g., floors, drains, walls, overhead structures).

Food Contact Surface – For purposes of this directive, a surface of equipment or a utensil with which exposed RTE product has direct contact (e.g., conveyor belt, tabletop, knife blade). A food contact surface does not include aprons, mop handles, gloves, and other items that may have indirect or potential contact with exposed RTE product.

Food Contact Surface Samples – A collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

High or Medium Risk Operation – For purposes of this directive,

A. All establishments defined as large in the July 26, 1996 Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (PR/HACCP) final rule that produce any amount of high or medium risk product;

B. Any establishment defined as a small or very small establishment in the July 26, 1996 final rule that:

1. Produces a large volume of high or medium risk products;

2. Produces any volume of high or medium risk products and has a history of multiple or recurring sanitation (procedures 01B, 01C, 06D) noncompliance records (NRs) in the in the area of the facility where RTE product is exposed to the environment; or

3. Produces any volume of high or medium risk products and is operating under conditions that have historically been associated with findings of *L. monocytogenes* on product or in the environment (e.g., construction activity that may affect the presence of *Listeria*), but does not have a science-based control program to address this situation.

High or Medium Risk Products – For purposes of this directive, these RTE meat and poultry products are (1) deli-type products (high risk), which include, but are not limited to the following products that either are sliced in the establishment or likely will be sliced at retail (e.g., at a deli counter): cured ham, roast beef or turkey, bologna, luncheon meat, pastrami, and other cold cuts; (2) hot dog-type products (medium risk), which include any meat or poultry products that are cooked sausages -- such as wieners or frankfurters of the type specified in 9 CFR 319.180, 319.181, or a variation of these standardized products; and (3) deli- and hot dog-type products that **have not** been formulated or **are not** produced and distributed under conditions validated to prevent the growth of *L. monocytogenes*.[9]

Indicator Organisms – For purposes of this directive, bacteria often used as an indicator for potential presence of a pathogen, not necessarily the pathogen itself. *Listeria spp.* and *Listeria*-like organisms are frequently used as an indicator organism for the potential presence of *L. monocytogenes* contamination.

Lethality Treatment – For purposes of this directive, lethality treatment refers to the necessary reduction in the number of pathogens to result in a product that is safe for consumption without further cooking or application of another lethality treatment to destroy pathogens.

Listeria monocytogenes* (*L. monocytogenes) – A type of pathogenic bacteria often found in the environments in which food producing animals are raised and processed (e.g., in soil, water, and vegetation, and on the surfaces of equipment, floors, and walls).

***Listeria* spp.** - The genus or group of microorganisms that include *L. monocytogenes*. *Listeria* spp. may be present in the processing environment but not all species are pathogens.

Low Risk Operation – For purposes of this directive, any establishment that produces low risk product and:

[9] These RTE meat or poultry products fit into the categories identified by the January 2001, Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, U.S. Department of Health and Human Services' Food and Drug Administration's Center for Food Safety and Applied Nutrition and the U.S. Department of Agriculture's Food Safety and Inspection Service.

A. Does not have a history of multiple or recurring sanitation (procedures 01B, 01C, 06D) noncompliance records (NRs) in the in the area of the facility where RTE product is exposed to the environment; and

B. Has a science-based control program to address conditions that have historically been associated with findings of *L. monocytogenes* on product or in the environment (e.g., construction activity that may affect the presence of *Listeria*).

Low Risk Products – For purposes of this directive, these RTE meat and poultry products are deli-type products (i.e., products that either are sliced in the establishment or will be sliced at retail) and hot dog type-products (i.e., 9 CFR 319.180-type) that **have been** formulated or **are** produced and distributed under conditions validated to prevent the growth of *L. monocytogenes.* These products are stable with respect to growth of *L. monocytogenes* by any of the following means:

- pH < 4.5
- pH < 5.0 + refrigerated storage
- a_w < 0.90 (NOTE: a_w refers to water activity)
- a_w < 0.92 + refrigerated storage
- a_w < 0.95 + pH < 5.5
- the presence of an antimicrobial agent (e.g., sodium or potassium lactate, sodium diacetate) that has been validated through scientific studies to inhibit growth of *L. monocytogenes*
- Product that is held at or below 0°C (32°F) and is labeled "Keep Frozen" and does not meet the criteria for Not-RTE (see Attachment 2), or
- Product that has received a post-lethality treatment that has been validated to be lethal for *L. monocytogenes.*

Pathogen of Public Health Concern – Any microorganism or other biological agent that has the ability to cause disease in humans. For purposes of this directive, these pathogens include *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*.

Post Lethality Exposure – Exposure of RTE product directly to a food contact surface after the lethality treatment. Such exposures generally are the result of slicing, peeling, or re-bagging product that previously underwent a lethality treatment to result in RTE status.

Post Lethality Treatment – A lethality treatment after post-lethality exposure that is applied to the final product or sealed package and is intended to further reduce the level of potential pathogens, such as *L. monocytogenes*, in RTE products.

Prerequisite Program - For purposes of this directive, prerequisite programs are procedures other than Sanitation SOPs that are designed to provide the basic environmental and operating conditions necessary for the production of safe, wholesome food and to control *L. monocytogenes.* Because of its prerequisite program, an establishment may decide that a food safety hazard (e.g. *L. monocytogenes*) is not reasonably likely to occur in its operation. The establishment

would need to document this determination in its Hazard Analysis and include the procedures (e.g., regular auditing and documentation) it employs to ensure that the program is working and that the hazard is not likely to occur (9 CFR 417.5(a)(1)).

Ready-to-Eat (RTE) Product – Product that is intended to be consumed without any further safety preparation steps. FSIS will sample and test RTE products produced under the following processing categories:

A. not heat treated—shelf stable (9 CFR 417.2(b)(v), ISP HACCP process 03E)

B. heat treated—shelf stable (9 CFR 417.2(b)(vi), ISP HACCP process 03F)

C. fully cooked—not shelf stable (9 CFR 417.2(b)(vii), ISP HACCP process 03G)

D. product with secondary inhibitors—not shelf stable, (9 CFR 417.2(b)(ix), ISP HACCP process 03I).

NOTE: FSIS is aware that establishments may produce RTE and Not-RTE products under A, B, and D. Attachment 2 provides further guidance regarding how establishments and inspection program personnel may determine whether a product is RTE or Not-RTE. When collecting samples from these categories, inspection program personnel should only collect samples associated with RTE product or production. Also, for products that can be RTE or Not-RTE, inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance for a Not-RTE product as described in Attachment 2.

RTE Product Samples – A collection of sampled RTE product that represents the sampled lot. The samples are taken from product that has passed the establishment's pre-shipment HACCP review. The sampled product should be in its consumer-ready package whenever possible. When this is not possible (e.g., only bulk product is being produced and the immediate container is too large to ship), inspection program personnel may permit the establishment to short-weight or slack-fill the immediate container. In such cases, the sample must be produced and packaged in the same way as the product that it represents; the only difference would be that the contents of the package would be less than the contents of the packages that it represents. Minimum sample sizes for analysis are defined in FSIS Directive 10,210.1 or are provided in block 18 of the sample request form, FSIS Form 10,230-3.

RTE Production Area - An RTE production area is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for indicator organisms or *L. monocytogenes*.

Sampled Lot – Based on the establishment's definition of a lot, the sampled lot would be the amount of product represented by one or more product and food contact surface samples. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. In situations where recall, retention, or seizure

is necessary, FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's history of practices for setting lot size and the definition of lot size as defined in the establishment's sampling program; coding of product; the pathogen of concern; the processing and packaging; the equipment; the decision-making documents that the establishment is required to maintain under 9 CFR 417.5(a)(2); the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 9 CFR 417.2 and 417.4; the establishment's Sanitation SOP records as required in 9 CFR 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected, including whether the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products.

PART 2 - *LISTERIA* STATEMENT OF POLICY

GENERAL POLICY REGARDING *LISTERIA* IN HIGH, MEDIUM, or LOW RISK PRODUCTS

This section defines how FSIS will decide the frequency of the verification testing that it will perform in operations that produce deli-type products and hot dog-type products. FSIS inspection program personnel must determine the following: Whether the establishment is producing high or medium risk product or is producing low risk product; whether the establishment has a written science-based program that is part of the HACCP plan, Sanitation SOP, or prerequisite program; and whether the establishment makes available to FSIS all data collected as part of its validation and on-going monitoring and verification activities. See attachments 3 and 4 for flowcharts regarding the type of verification testing program for these products, and for determining the risk category associated with these products.

A. If the establishment produces high or medium risk products and does not have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment (i.e, in a HACCP plan, Sanitation SOP, or prerequisite program), or has these programs and does not make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its intensified verification program (Part 3, I.A.).

B. If the establishment produces high or medium risk products and does have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment, and does make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its targeted verification program (Part 3, I.B.). If such establishments receive a positive test result for *L. monocytogenes* from FSIS testing, FSIS will consider placing them into the intensified verification program until corrective actions are successful.

C. If the establishment produces low risk products and does not have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and

the environment (i.e, in a HACCP plan, Sanitation SOP, or prerequisite program), FSIS will place this operation into its intensified verification program (Part 3, I.A.).

D. If the establishment produces low risk products and:

1. Does have a science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment, and does make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its low-targeted verification program (Part 3, I.C.).

2. Does have the science-based program identified in D.1 above but does not make data from its testing available to FSIS inspection program personnel, FSIS will place this operation into its targeted verification program. If this establishment receives a positive test result for *L. monocytogenes* from FSIS testing, FSIS will consider placing this operation into the intensified verification program until corrective actions are successful.

PART 3 – RTE PRODUCT, FOOD CONTACT SURFACE, AND ENVIRONMENTAL SAMPLING

I. VERIFICATION TESTING BY FSIS

A. Intensified verification testing program. This program includes, but is not limited to, high, medium, and low risk products produced in establishments that operate under the conditions specified in Part 2 for establishments placed into the intensified verification testing program. When samples of RTE product are scheduled for collection, this program may include instructions to inspection program personnel to collect multiple product, food contact surface, and environmental samples which are intended to be collected on the same day. As a general matter, FSIS will focus its testing in high and medium risk operations. Intensified verification testing will include:

1. Increased frequency and number of samples taken of product for testing (as compared to targeted verification testing) for pathogens of public health concern, and the collection of food contact surface and environmental samples for testing for *L. monocytogenes,* and

2. Increased FSIS record verification checks regarding the implementation of the food safety system, as directed by the frontline supervisor.

B. Targeted verification testing program. This program includes high, medium, and low risk products produced in establishments that operate under the conditions specified in Part 2 for establishments placed into the targeted verification testing program. This program also includes all other RTE products except those under the low-targeted verification testing program described in paragraph C and those under the non-targeted verification testing program listed in paragraph D. FSIS randomly collects one sample of product at a time from an individual establishment and tests for pathogens of public health concern.

C. Low-targeted verification testing program. This program includes low risk products produced in establishments that operate under the conditions specified in Part 2 for establishments placed into the low-targeted verification testing program. In addition, this program includes RTE products other than low risk products that have been formulated or are produced and distributed under conditions validated to prevent the growth of *L. monocytogenes* (see Low Risk Products for a listing of the means by which products are stable with respect to growth). These products, particularly those from low risk operations, will be scheduled at a decreased frequency for product testing (as compared to targeted verification testing) for pathogens of public health concern. FSIS randomly collects one sample of product at a time from an individual establishment and tests for pathogens of public health concern.

D. Non-targeted verification testing program. FSIS will direct inspection program personnel to collect product samples, as necessary, in operations that exclusively produce the types of products listed below:

a. Lard,
b. Margarine,
c. Lard margarine,
d. Mixtures of rendered animal fats,
e. Popped pork skins,
f. Pork rinds,
g. Dried soup bases,
h. Concentrated (high salt content) soup mixes,
i. Pickled pig's feet, or
j. Product labeled "For Further Processing" in which the product is expected to receive a lethality treatment

II. SAMPLING

A. Product and pathogen selection. FSIS Directive 10,210.1 Amendment 3, Unified Sampling Form, lists the products and pathogens for which FSIS may test samples. For example, FSIS may analyze a not heat treated, not shelf stable RTE meat and poultry product for *Salmonella* AND *L. monocytogenes*, and if the product is a dry or semi-dry fermented beef sausage, the product will also be analyzed for *E. coli* O157:H7.

B. Notification of sample request. When the Office of Public Health and Science (OPHS) schedules a sample from a lot of RTE product to be taken at an establishment, the Inspector-in-Charge (IIC) receives FSIS Form 10,210-3, "Requested Sample Programs" from OPHS. Generally, only one sample request form will be sent to the IIC. The District Office (DO) will coordinate the random sampling of a lot of high, medium, or low risk product and the collection of environmental samples. When the forms are sent, certain blocks will be preprinted with information specific to the sample to be collected. Using the project code in Block 14 of the forms, follow the corresponding instructions found in FSIS Directive 10,210.1, Amend. 3 for collecting and shipping samples.

C. Informing the establishment regarding sample collection. Inspection program personnel should provide the establishment management enough time to hold all product that the establishment determines to be represented by the sample (i.e., the sampled lot). In some cases, inspection program personnel may need to inform the establishment a number of hours or days in advance, such as for establishments operating under an extended clean-up or because of the production process involved (e.g., the production of dry and semi-dry fermented sausages).

D. Informing the establishment about holding product. Establishments are not required to hold product represented by the sampled lot. However, to reduce the risk of a recall, FSIS recommends that establishments should hold product represented by the sample until the test results confirm that a pathogen of public health concern is not present in product or food contact surface samples.

E. Personnel collecting samples. Inspection program personnel will collect product samples. However, trained program personnel other than the in-plant inspection employees may be directed to collect food contact surface and environmental samples (i.e., the samples from the food contact surface, the indirect food contact surface, and the surfaces that do not contact food). The collection of food contact surface and environmental samples is not intended to replace product sampling by FSIS. These non-product samples will provide helpful information to FSIS regarding the sanitary conditions in the RTE production area of the establishment, but special skills and training are required in order to collect these non-product samples.

F. Sample collection and submittal timeframes. If possible, **only** collect and mail the samples from the establishment's current day's production that has passed the establishment's pre-shipment record review (see 9 CFR 417.5(c)). If not possible, such as in establishments where production is held off-site prior to completion of the pre-shipment record review, or the pre-shipment record review is performed at a later date, collect samples of the current day's production, refrigerate or freeze them, keep them in a secure location, and postpone mailing the samples until the pre-shipment record review is complete, and the product is eligible for shipment. After the establishment completes the pre-shipment record review, inspection program personnel should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

G. Sample collection decisions. Any in-plant sampling for *L. monocytogenes* to be performed under the intensified verification testing program will be coordinated through the DO. Any sampling of establishments under the targeted, low-targeted, and non-targeted verification testing program is performed by the in-plant inspection program personnel as per the sample request form. If a change in operations or conditions at an establishment results in a need to change the establishment to the intensified verification testing program (e.g., type of product produced changes; construction), the in-plant inspection program personnel would notify their frontline supervisor. The inspection program personnel in the plant would have a first-hand knowledge about the operations in that establishment. FSIS may direct the inspection program personnel to pull additional samples, but such instructions would come from the DO and specially trained inspection program personnel would collect any food contact or environmental samples in these situations.

H. Completion of sample request form and inspection procedure. Sample request form. Complete all requested information in Part 2 of the FSIS Form 10,210-3, as described in FSIS Directive 10,210.1, Amend. 3. The FSIS laboratories will discard any samples with incomplete forms.

III. FSIS ACTIONS WHEN PRODUCT, FOOD CONTACT SURFACE, OR ENVIRONMENTAL SAMPLES ASSOCIATED WITH HIGH, MEDIUM, OR LOW RISK PRODUCT TEST POSITIVE FOR *LISTERIA*

A. Product Testing by FSIS or the Establishment for *L. monocytogenes*

When an FSIS or establishment product sample tests positive for *L. monocytogenes,* the sampled lot is adulterated and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped.

B. Food Contact Surface Testing by FSIS or the Establishment for *L. monocytogenes*

When an FSIS or establishment food contact surface sample tests positive for *L. monocytogenes,* product from the sampled lot is adulterated, and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 5400.5, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped. (NOTE: On a case-by-cases basis, for low risk products that have a post-lethality treatment subsequent to contact with the implicated food contact surface, and the treatment has been validated to be lethal for *L. monocytogenes*, FSIS will determine whether to request a recall).

C. Environmental Testing by FSIS for *L. monocytogenes*

When an indirect or a non-food contact surface sample from the RTE production area collected by FSIS tests positive for *L. monocytogenes*, inspection program personnel are to take the appropriate action as set out in FSIS Directive 5400.5 and FSIS Directive 11,000.1 and inform the establishment so that the establishment can take corrective actions as described in its HACCP Plan, Sanitation SOP, or prerequisite program, or to reassess these programs if they do not include corrective actions for the presence of this pathogen in the environment. Trained inspection program personnel may be directed to take additional environmental samples, as well as food contact surface and product samples.

D. Food Contact Surface Testing by the Establishment for Indicator Organisms

1. If a food contact surface sample tests positive for indicator organisms (the establishment is not testing for *L. monocytogenes;* thus, FSIS would not have a basis to definitively conclude that the product is adulterated) in an establishment's testing program, inspection program personnel are to verify that the establishment takes the corrective actions it has developed, whether as part of a HACCP plan, Sanitation SOP,

or prerequisite program as specified in FSIS Directive 5000.1, FSIS Directive 5400.5, FSIS Directive 11,000.1, and FSIS Notice 29-02.

2. FSIS expects that a properly designed, science-based preventative program for *L. monocytogenes* will include features such that the establishment takes additional steps to thoroughly clean and sanitize potentially contaminated food contact surfaces and increase the number of food contact surface samples that it takes, particularly of the areas represented by the initial positive, in an effort to find the source of the contamination and to prevent harborage. If any of these follow-up samples are positive as a consequence of this intense searching for potential sources of contamination, inspection program personnel are to verify that the establishment takes the corrective actions it has developed. A properly designed, science-based preventative program may include procedures such as holding and testing product after corrective actions in order to verify that harborage has been prevented. In such cases, inspection program personnel are to verify that the establishment has identified and implemented the conditions in which hold and test procedures for affected product will be initiated by the establishment and the conditions in which hold and test procedures for affected product will be terminated by the establishment.

3. On an ongoing basis, inspection program personnel are to review the laboratory results of the establishment's food contact surface testing program. If multiple positive samples for indicator organisms are detected, either within consecutive samples or non-consecutive samples within a relatively short time span, and the establishment did not take the corrective and preventative action outlined in the establishment's plan, inspection program personnel should immediately contact their frontline supervisor. A CSO may be assigned by the DO to review the control measures included in HACCP plans, Sanitation SOPs, or prerequisite programs. The CSO will assess the establishment's total system to verify that the establishment has designed its testing procedures so that if indicator organisms or *L. monocytogenes* are detected, the establishment has in place procedures to effectively address their presence. The CSO will review written procedures, assess decision-making documents for completeness and rationale, and review laboratory results.

E. Environmental Testing by the Establishment for Indicator Organisms or *L. monocytogenes*

When an indirect or a non-food contact surface sample from the RTE production area collected by the establishment tests positive for an indicator organism or *L. monocytogenes*, inspection program personnel are to verify that the establishment has taken corrective actions as described in the establishment's HACCP Plan, Sanitation SOP, or prerequisite program. Trained FSIS inspection program personnel may be directed to take environmental samples, as well as food contact surface and product samples.

IV. FSIS ACTIONS WHEN PRODUCT SAMPLES ASSOCIATED WITH ANY RTE PRODUCT OTHER THAN HIGH, MEDIUM, OR LOW RISK PRODUCT TEST POSITIVE FOR A PATHOGEN OF PUBLIC HEALTH CONCERN

When an FSIS or establishment product sample tests positive for a pathogen of a public health concern, including *L. monocytogenes,* the sampled lot is adulterated and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped.

V. FSIS ACTIONS WHEN FOOD CONTACT SURFACE SAMPLES ASSOCIATED WITH ANY POST-LETHALITY EXPOSED RTE PRODUCT OTHER THAN HIGH, MEDIUM, OR LOW RISK PRODUCT TEST POSITIVE FOR *L. MONOCYTOGENES*

When an FSIS or establishment food contact surface sample tests positive for *L. monocytogenes*, the sampled lot is adulterated and inspection program personnel take the appropriate action as set out in FSIS Directive 5000.1, FSIS Directive 11,000.1, and FSIS Notice 29-02. FSIS will request a recall if any product in the sampled lot has been shipped. (NOTE: On a case-by-case basis, for RTE products that have a post-lethality treatment subsequent to contact with the implicated food contact surface, and the treatment has been validated to be lethal for *L. monocytogenes*, FSIS will determine whether to request a recall).

Refer technical questions to the Technical Service Center.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy and Program Development

QUESTIONS AND ANSWERS
(Attachment 1)

SAMPLE COLLECTION

1. **Question:** Are establishments required to hold the lot that is sampled?

   Answer: No. Establishments are not obligated to hold any product when inspection program personnel collect samples. As has been FSIS policy and practice as instructed in FSIS Directive 10,210.1, inspection program personnel are to notify establishments sufficiently early to provide them the opportunity to hold the entire lot represented by the sample. Establishments' willingness to hold sampled lots becomes an important public health benefit if a sampled lot is found to be positive for a pathogen. Inspection program personnel will ensure that plants are appropriately notified.

2. **Question:** When should inspection program personnel submit samples?

   Answer: The pre-shipment review must be completed before the samples are sent to the laboratory for analysis.

3. **Question:** If a sample is collected on a Friday but not picked up by Federal Express on that day, and if the next scheduled pick up is Monday, can the sample be kept in the cooler or freezer until Monday and then shipped?

   Answer: Inspection program personnel should try to avoid holding samples over the weekend whenever possible because the establishment would most likely be holding the sampled lot. If Federal Express cannot pick up the sample on the day of collection, inspection program personnel can refrigerate or freeze the sample until it can be picked up. However, inspection program personnel should not hold samples for more than three days (i.e., Friday to Monday) prior to shipping.

4. **Question**: If inspection program personnel already have sample requests forms issued under FSIS 10,240.2, what should they do?

   Answer: With the issuance of FSIS Directive 10,240.3, Directive 10,240.2 (including Section VIII of that Directive) was canceled. With Directive 10,240.3, there no longer is any condition in which establishments can get "exempted" from FSIS verification testing. Therefore, inspection program personnel should collect samples according to the timeframes identified on the sample request forms and regardless of whether the form was issued before or after implementation of FSIS Directive 10,240.3.

5. **Question**: Will existing RTE sample request projects (HV03E, HV03F, HV03G, and HV03I) be terminated?

Answer: At this time, FSIS expects to terminate these specific programs and identify new project codes with new names. Although the December 2002 forms have already been generated and distributed with these project codes, FSIS now expects to issue the January 2003 and subsequent sample request forms with the project code "Targeted." December 2002 forms should be collected as normal following the instructions on the form and FSIS Directive 10,210.1. The forms for January 2003 and subsequent months should be collected following the new instructions on the form and referencing FSIS Directive 10240.3. If you have any questions on collecting RTE samples, please contact the Technical Service Center for assistance.

SAMPLE RESULTS

6. **Question:** If an establishment delivered product from a sampled lot to a customer but retrieved all of it before the report of the FSIS sample result, will the product be deemed to have been shipped?

   Answer: Yes, once an establishment completes its pre-shipment record review, the product is considered as "shipped" or "eligible for shipment." Upon report of a positive result, establishments are expected to prevent product from entering commerce in accordance with sections 9 CFR 417.3(a)(4) or (b)(3) of the regulations and to treat it in a manner that will make it no longer adulterated. Product adulterated with a pathogen that is not treated in such a manner will be condemned. Inspection program personnel are not to take any regulatory control actions unless the establishment fails to control product as specified in 9 CFR 417.3(a)(4) or (b)(3).

7. **Question:** If an FSIS product or food contact surface sample tests positive, what is the status of product(s) produced on days subsequent to the day the sample was collected?

   Answer: In general, FSIS does not consider product that is produced on days subsequent to the day of sampling and that is coded differently from the sampled lot to be represented by the sample, and under most circumstances not subject to retention, detention, or voluntary recall. A positive sample does call into question the adequacy of an establishment's process for producing safe product. Upon report of a positive sample, inspection program personnel will perform the appropriate HACCP 02 procedure on the product's HACCP plan, and an 01B01 and an 01C01 procedure on the establishment's Sanitation SOPs covering the time period from when the sample was collected to the present. If the findings of these procedures indicate that the establishment shipped adulterated product other than the sampled lot, this additional product would be subject to detention, voluntary recall, or seizure. For example, if inspection program personnel found that the establishment failed to meet the critical limit at the cooking CCP and took no corrective action on subsequent lots, all product affected by this failure is subject to retention, detention, voluntary recall, or seizure.

8. **Question:** Does a sample test result that is positive for *Listeria* spp. microorganisms indicate that the product is adulterated?

   Answer: No. However, FSIS considers a finding of *Listeria spp*. microorganisms on product or a food contact surface to be an indication that the process may not be appropriately controlled. In high or medium risk operations, FSIS intends to conduct intensified verification reviews of the establishment's food safety system when *Listeria* spp. or *Listeria*-like results are found and there is no scientifically-based procedure in place to address this sanitation concern. This may include taking new verification samples of product and of the environment.

9. **Question:** If a RTE product tested by FSIS is found positive for a pathogen, is the HACCP plan automatically inadequate, and should the inspector immediately take a withholding action?

   Answer: Not necessarily. As noted in the directive, the Agency will take into account all available information and consider the entire situation before making a determination of HACCP plan inadequacy. The cause and significance of a positive result varies from case to case based on the pathogen found, and the circumstances of processing involved. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3. In regard to a withholding action, inspection program personnel will follow the procedures in FSIS Directive 5000.1, Part II and III, and 9 CFR Part 500. If the IIC determines, based on the available information, that the establishment is continuing to produce and ship product that may be injurious to health, he or she should withhold the marks of inspection and inform the DO.

10. **Question:** If an establishment tests for indicator organisms and has a second positive result for indicator organisms does this mean that the establishments control and testing programs that are incorporated into their Sanitation SOPs or prerequisite programs are automatically invalid?

    Answer: No. FSIS will take into consideration how the establishment responds to the positives, the type of intensified testing the establishment conducts, and the conditions that may have led to the second positive. In some cases, the second positive may have occurred from lack of proper execution of control programs and in other cases may indicate a design problem. In cases that involve a design problem such that there are repetitive positive findings, FSIS may place the establishment into the intensified testing program until FSIS determines that the establishment has implemented the proper corrective and preventive measures.

11. **Question:** Can establishments use product that tested positive for a pathogen as "re-work?" Are there special restrictions?

Answer: The regulations do not prohibit the use of product that tested positive for a pathogen as "re-work." An establishment is expected to address the use of such product in its HACCP plan. The plan must address any hazards presented by the practice such as the potential hazard of increased tolerance of bacteria that survived a "kill" step. If the practice of re-working such product is done all the time, then critical limits and CCPs need to account for any potential added hazards. If the practice is done occasionally, the plan may only need to address the procedures, critical limits, and CCPs to be met when lots containing re-work are processed. When product that tested positive is identified after it has left an establishment, it may be moved under control to an establishment where it can be further processed.

FOLLOW-UP SAMPLING

12. **Question:** During follow-up verification sampling that may be scheduled from headquarters, must the samples be collected on consecutive production days?

Answer: The form should come with a note that instructs the inspection program employee to collect the samples within 60 days, if possible. Samples do not have to be collected on consecutive production days. The purpose of the follow-up sampling is to verify the effectiveness of the establishment's corrective and preventive measures.

INSPECTION ACTIVITIES

13. **Question**: When an environmental sample (indirect or non-food contact) taken in an RTE production area by FSIS under the intensified verification program results in a positive finding of *L monocytogenes,* how do inspection program personnel document the finding?

Answer: Inspection program personnel should document the sample result on an NR using procedure code 06D01, with the trend indicator Facility/Product Based. In addition, the NR should reference 416.4(b) as the regulatory citation.

14. **Question:** When a food contact surface sample taken in an RTE production area by FSIS under the intensified verification program results in a positive finding of *L monocytogenes*, how do inspection program personnel document the result?

Answer: Inspection program personnel should document the sample result on an NR using procedure code 01C02, with the trend indicator Sanitation SOP/Implementation. In addition, the NR should reference 416.14 as the regulatory citation.

15. **Question:** If an establishment has a science-based environmental sampling program incorporated into its HACCP plan, Sanitation SOP, or prerequisite program and its sample of a food contact surface results in a positive finding of *L monocytogenes,* what should inspection program personnel do?

Answer: Inspection program personnel should verify that the establishment has taken the appropriate corrective action, as outlined within the establishment's

environmental sampling program, and all regulatory requirements have been met. If the program is contained within the establishment's HACCP plan, inspection program personnel should verify that the requirements within 417.3 (a) are met. If the program is contained within the establishment's Sanitation SOPs, inspection program personnel should verify that the requirements within 416.15 are met. If the program is contained within a prerequisite program, inspection program personnel should verify that all procedures outlined within the program are followed.

16. **Question:** If an establishment's food contact surface sample results in a positive finding of *L monocytogenes* and the establishment does not take corrective action as outlined in their science-based environmental sampling program, how do inspection program personnel document this?

Answer: The type of documentation will depend on where in the establishment's food safety system the environmental sampling procedure is addressed.

- If the establishment's sampling program is addressed within their Sanitation SOPs, inspection program personnel should write an NR using procedure 01B01 or 01C01, whichever is appropriate, with the trend indicator Sanitation SOP/implementation. In addition, the NR should reference 416.14 as the regulatory citation.
- If the establishment's sampling program is addressed within their HACCP plan, inspection program personnel should write an NR using the appropriate HACCP 03 procedure with the trend indicator HACCP/Corrective Action. In addition, the NR should reference 417.3(a) or (b), whichever is appropriate, as the regulatory citation.
- If the establishment's sampling program is addressed outside of their HACCP plan or Sanitation SOPs, as a prerequisite program supporting their hazard analysis, inspection program personnel should write an NR using the appropriate HACCP 03 procedure with the trend indicator HACCP/Recordkeeping. In addition, the NR should reference 417.5 (a)(1) as the regulatory citation.

17. **Question**: Are there situations in which inspection program personnel may submit an inspector-generated sample?

Answer: Yes, depending on situations taking place within the establishment, inspection program personnel may feel that it is necessary to request permission for collecting and submitting an inspector-generated sample. For example, an establishment produces a low risk product and is in the low-targeted verification testing program. Inspection program personnel observe that the establishment has modified the production process for this product and it no longer satisfies the conditions for low risk; the product now is a high risk product but the establishment has not modified its environmental control program to address this situation. In this situation, after consulting with his or her frontline supervisor, inspection program personnel obtain permission to collect the sample, and obtain FSIS 10,210-3 Requested Sample Form through channels from the Office of Public Health and Science prior to collecting a "for cause" sample. Remember, inspection program

personnel are to consult with his or her frontline supervisor before taking any inspector-generated sample.

18. **Question**: If inspection program personnel have not received a sample request form in a number of months, should he or she take an inspector-generated sample?

Answer: No, inspector-generated samples should not be submitted solely because the inspector has not received a generated sample request in the past few months. Under its sampling programs, FSIS will concentrate its resources on high or medium risk operations that do not have science-based programs or that do not share their data. Consequently, there may be times when certain products and operations will be sampled less frequently than in the past.

19. **Question:** If an establishment is utilizing sliced deli meats or hot dogs in a Heat Treated, but not Fully Cooked, Not Shelf-Stable product (Not-ready-to-eat) multi-component product such as a frozen meal, dinner, entree, or hot sandwich, are the finished products or in-process deli-meats or hot dogs categorized as a high or medium risk product and subject to the intensified verification testing program?

Answer: If the meat or poultry component received an adequate lethality treatment for pathogens; cooking and preparation instructions on the product are sufficient to destroy pathogens; instructions are realistic for the intended consumer and proper caution statements such as those described in Attachment 2, ISP 0H3 are utilized, the finished product as well as the sliced deli meat portion or hot dogs would not be categorized as high or medium risk product and are not subject to the intensified verification testing program.

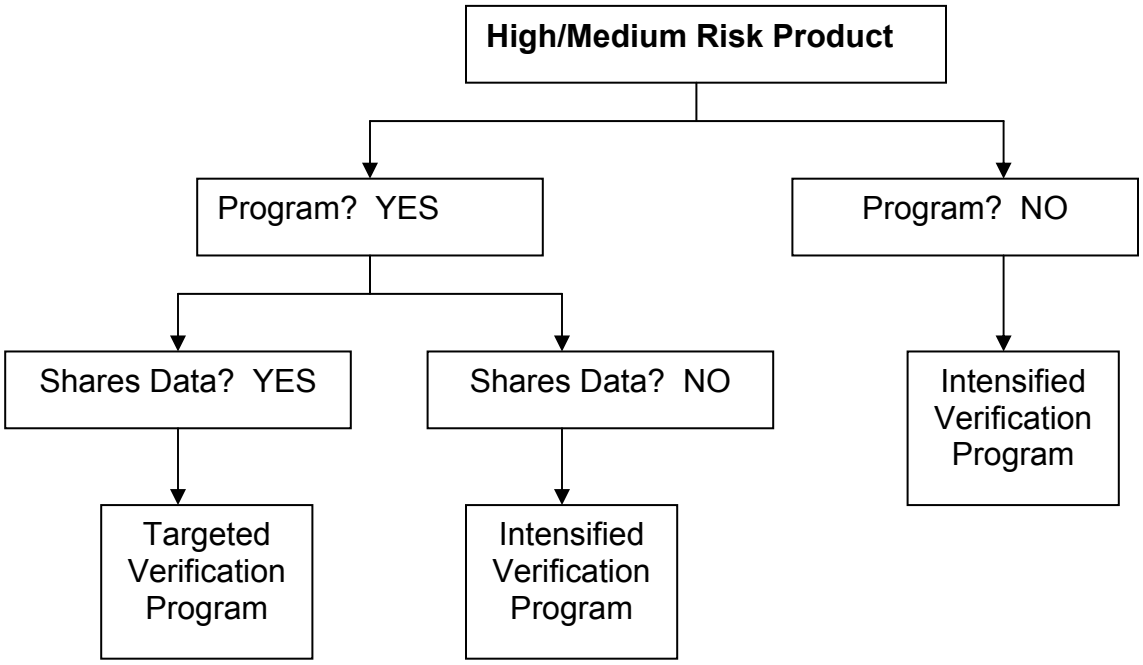
20. **Question:** What are the expectations regarding environmental testing for low risk products that receive a post-packaging lethality treatment validated to destroy any *L. monocytogenes* that might be present?

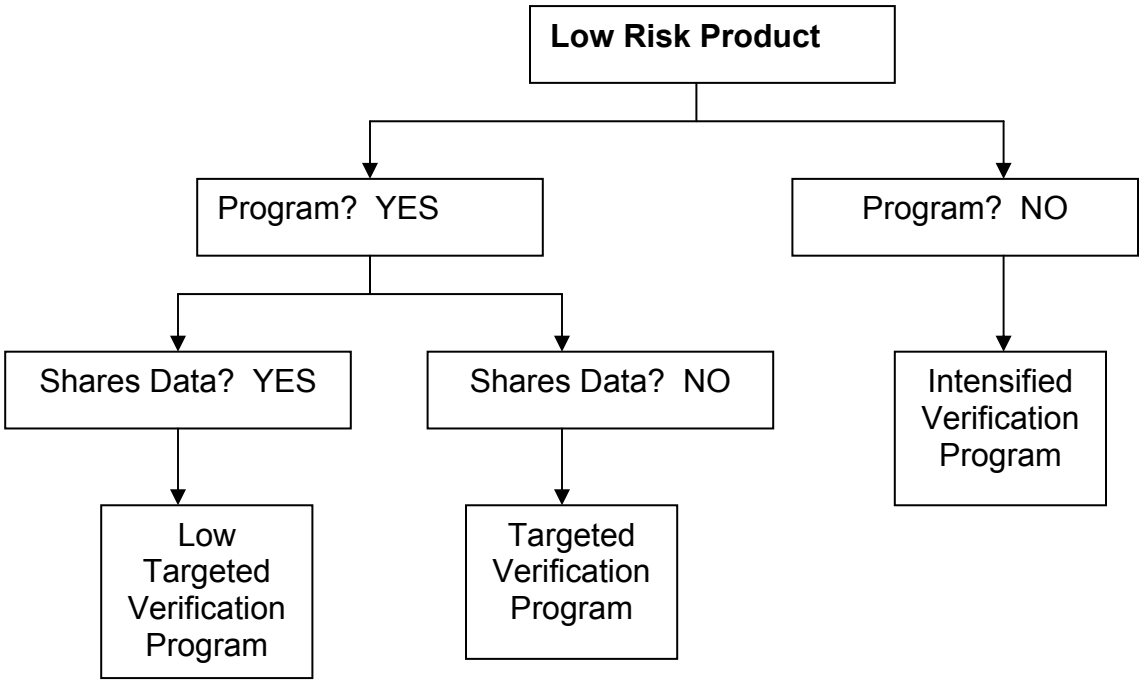
Answer: The FSIS public health focus is on products that have a greater likelihood of becoming contaminated after the lethality step, and on products that support the growth of *L. monocytogenes*. Products that receive a lethality treatment after they are in their final packaging, validated to be effective under the operational conditions in the establishment, are unlikely to become further contaminated. In addition, such establishments may not routinely test food contact surfaces or the environment where these products are produced.

Attachment 2

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 03I •	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.
A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user.	Ready-to-eat	• Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	• See part 417 of the meat and poultry regulations.

Attachment 3
Flowchart: Verification Testing Program for High, Medium, and Low Risk Products





Attachment 4
Flowchart: Determining Risk of Product and Operation